09/600952

534 Rec'd PCT/PTC 25 JUL 2000

IN THE US PATENT AND TRADEMARK OFFICE

Inventors: CHOSACK et al.	§	
US Application No.: **not assigned**	§	
claiming priority from: International Application No.: PCT/IL99/00028	§	
International Filing Date: January 15, 1999	§	
Priority Date: January 26, 1998	§	
For: ENDOSCOPIC TUTORIAL SYSTEM	§	Attorney Docket: S02/11

Commissioner of Patents and Trademarks
Washington, D.C. 20231
USA

TRANSLATED ANNEX TO IPER
ACCOMPANYING NATIONAL PHASE APPLICATION

Sir:

Enclosed please find a copy of the above-referenced translated annex to the International Preliminary Examination Report under PCT Article 36, which is a translation of the cited reference PCT Application No. WO 91/06935, and which is respectfully submitted with the filing of the above-referenced National Phase Application.

Respectfully submitted,

D'vorah Graeser
Reg. No. 40,000

Date: July 20, 2000

09/600952
534 Rec'd PCT/PTC 25 JUL 2000

Computerized Simulation System for Human Surgery

The practicing of diagnostic and therapeutic surgery in medicine and advanced medicine studies is lacking. Therefore, the only option remaining is to practice on living patients, and learn the necessary material under the guidance of an experienced physician. However, because an experienced physician is frequently unable to rush for help, it may cause an irresponsible endangerment of the patients. This problem prevails not only in the medicine and the advanced medicine studies, but also in later medical practice, since certain medical operations and procedures are so rarely performed, that the physician loses the touch of routine. In the wake of the above, the following invention wishes to present a simulation system for diagnostic and therapeutic operations, examinations, therapeutic procedures, experimentation of new dangerous procedures, and treatment of all organs and/or openings of the human body.

According to the invention, this task is carried out through the distinctive marks in Patent Argument No. 1. The system comprises of a dummy human body, including all body openings (that lead into the cavities within). The body openings are thus built, to allow a sensor to be entered into them. This way, a sensor examination may be performed through each of the human body openings, using movable sensors. In other versions, the said sensors may be moved to all body organs (for example, for catheterization tests and/or follow-up of some action during the simulation).

These sensors allow one to precisely measure the location of the medical instrument point, or, in other words, the simulation of the instrument chosen for the given practice. The same is done by measuring the length, the angle and the rotation of the instrument. A sensor may also be installed on the device itself, which allows additional functions. This information leads to a simulation on a graphic computer. An integral part of the computer is a program, that draws the structure of simulated human body organ in the memory, in the picture data base. In addition, a realistic model may also be drawn of the simulated human body organ, with real electronic pictures (for example, video), for a data base.

The attached drawings clarify the matter of the system.

The attached drawings are :

Drawing No. 1 : System chart.

Drawing No. 2 : Schematic description of a simulation with the schematically described device.

A diagnostic and therapeutic instrument, in this case endoscope (A) is inserted for stomach examination. The said instrument is a light medical instrument, used in the medical practice. A sensor (1) is installed on this instrument, that together with a sensor (2) in the dummy human body (B and section) is able to measure the instrument's length, the angle and the rotation, thus the precise location of the diagnostic and therapeutic instrument's point may be determined in the human body (B). In this situation, the ends of the device are used as the information source. This information is transferred to the computer, where it is processed.

The computer in question is a picture processing real – time - computer. The manipulated object is presented accurately in the memory of this system, in the data base, or in other words, in the realistic model. For example, according to Drawing B, the stomach inner wall, including pathological changes. The picture data base is able, of course, to store all the human body organs. Based to the information received from the sensors, the computer finds the picture, relevant to the sensor's point location, and presents it on the screen, on real time. This function may be integrated in the diagnostic and therapeutic instrument, or may be performed separately.

As already said, the dummy human body is made of a flexible material, and it is used mainly for the insertion of a diagnostic and therapeutic instrument into the relevant body openings, in order to determine, through the sensor inserted into it, and with the help of the sensor installed on the device, , if at all, the precise location of the examination point.

Another important part is a computerized stoppage and/or braking device (3). This element performs resistance simulation, encountered by the diagnostic and therapeutic instrument during the examination. The above braking device (3) is activated when during the simulation it "feels" that the diagnostic and therapeutic instrument touches the examined organ (for example, the esophagus or bones).

The software

The software is able to draw pictures, based on the information received from the sensors or from the realistic model in the picture data base, and to present the said picture on the screen, either processed or not.

A unique characteristic is that the picture data base may be changed, through the computer (for example, complement a disease information).

There are also elements in the system, that perform statistical analysis and simulation errors analysis.

In addition, the system is capable of presenting to the "students" the "successful" process of examination, enabling them to learn the most innovative examination methods and the ways to perform them.

In addition, the system may be thus installed to allow also review and simulated experiment of state of the art surgery methods.

The Patent's Arguments

1. A computerized simulation system of diagnostic and/or therapeutic surgery on the human body, characterized by a dummy human body with a sensor located in the simulation area; and this sensor and the sensors of a diagnostic and/or therapeutic instrument transfer measurement values in the shape of sensor information to a computer with a picture data base; and the computer presents a visual picture on the screen, based on the sensor information, the performer's data, and the picture data base.

2. A system according to Argument No. 1, characterized by the sensor being movable; and the pictures required for the same may be seen on the human body description.

3. A system according to Argument No. 2, characterized by the sensor being equipped with a code, that transfers the respective area of the picture data base to the computer.

4. A system according to Arguments 1 to 4, characterized by a viewing system being integrated in the diagnostic and/or therapeutic device.

5. A system according to Arguments 1 to 4, characterized by the diagnostic and/or therapeutic device being equipped by at least one more sensor, for the simulation of additional devices.

Drawing No. 1

1 - Body

2 - Picture part

3 - Diagnostic and/or therapeutic instrument

4 - Sensor part

5 - Stoppage and brake device

6 - Drawing a picture

7 - Sensor information

8 - Stoppage and/or brake information

9 - Computer – picture data base

10 - Substitute page

11 - Operating channel

12 - Picture A – diagnostic and therapeutic instrument

13 - Double rotating head to operate the point

14 - Information from the sensor to the computer

15 - Computer information in the form of a picture

16 - Electric cord (lighting etc.)

17 - Picture B – body dummy

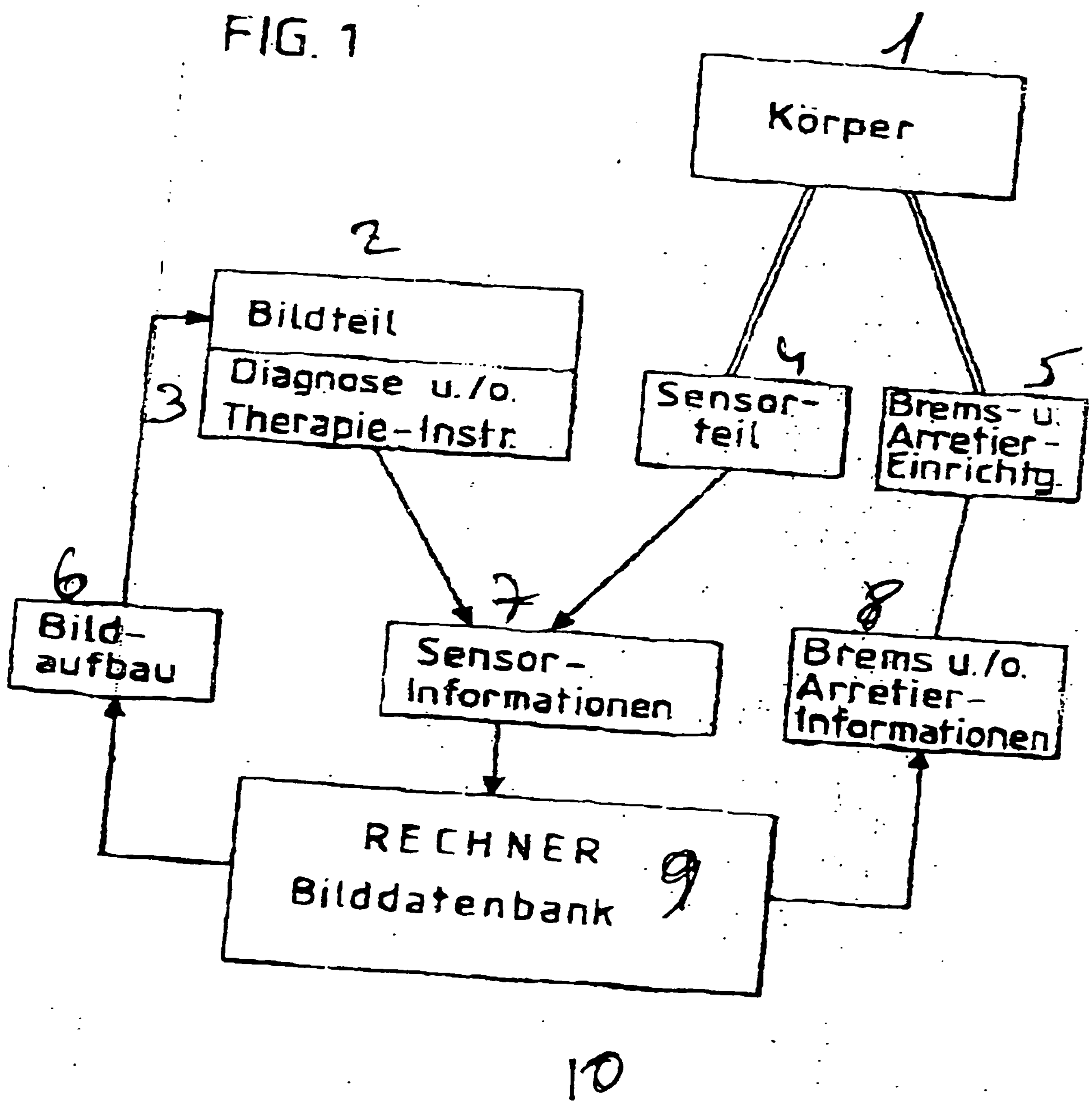
18 - Movable sensors, for example, mouth, rectum, body functions

19 - Braking and stoppage signals from the computer

20 - Information from the sensor to the computer

21 - Substitute page

FIG. 1


1
Körper
2
Bildteil
Diagnose u./o.
Therapie-Instr.
3
4
Sensor-
teil
5
Brems- u.
Arretier-
Einrichtg.
6
Bild-
aufbau
7
Sensor-
Informationen
8
Brems u./o.
Arretier-
Informationen
RECHNER
Bilddatenbank
9
10

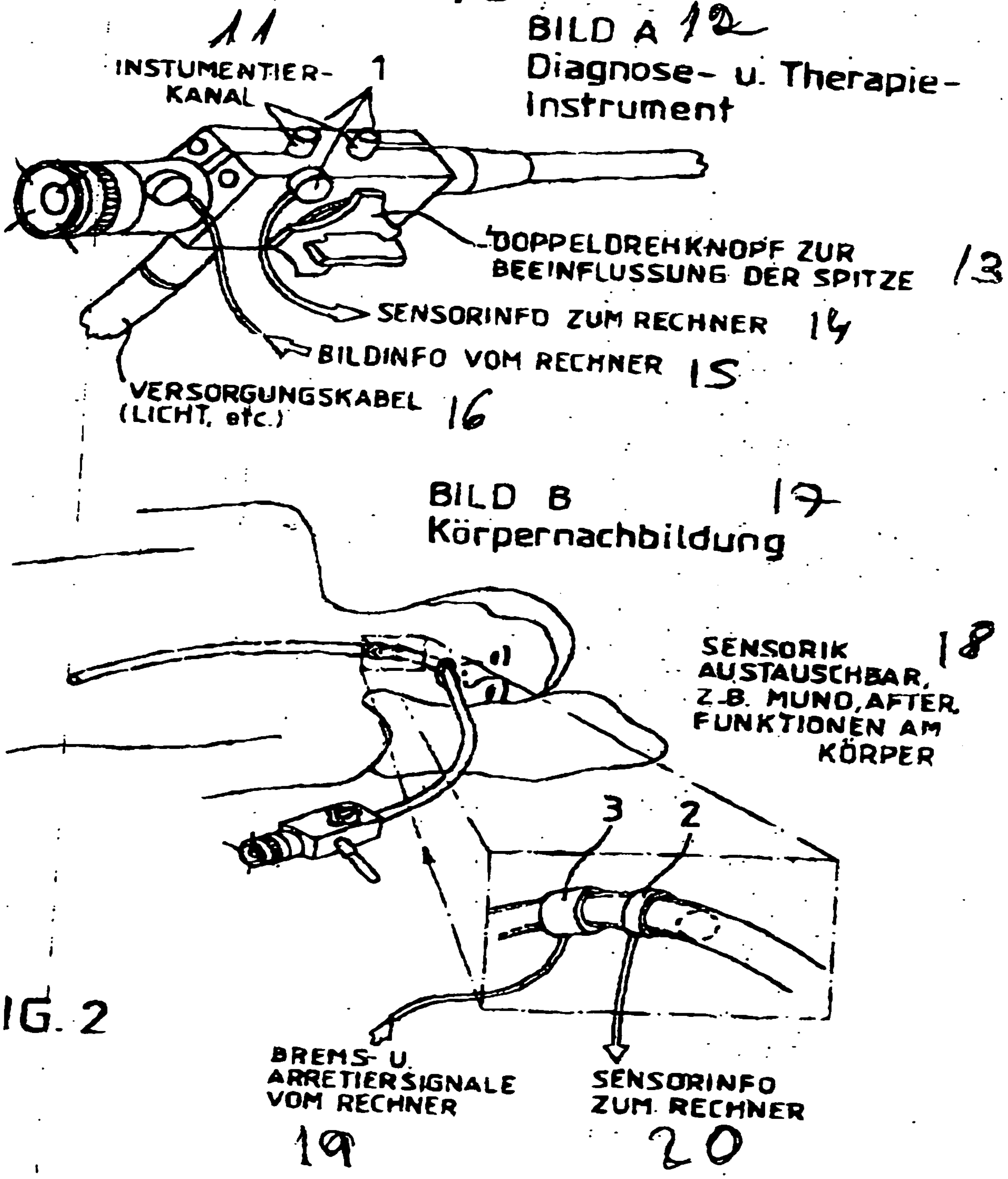


FIG. 2

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IN THE US PATENT AND TRADEMARK OFFICE

Inventors:
CHOSACK et al.

US Application No.: **not assigned**

claiming priority from:
International Application No.: PCT/IL99/00028

International Filing Date: January 15, 1999

Priority Date: January 26, 1998

For: ENDOSCOPIC TUTORIAL SYSTEM

Attorney
Docket: S02/11

Commissioner of Patents and Trademarks
Washington, D.C. 20231
USA

FIGURES SUBSTITUTED UNDER RULE 26
ACCOMPANYING NATIONAL PHASE APPLICATION

Sir:

Enclosed please find a copy of the above-referenced Figures, which were substituted under PCT Rule 26, and which are respectfully submitted with the filing of the above-referenced National Phase Application.

Respectfully submitted,

D'vorah Graeser
Reg. No. 40,000

Date: July 20, 2000

PATENT COOPERATION I REATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 22 November 1999 (22.11.99)	
International application No. PCT/IL99/00028	**Applicant's or agent's file reference** 1220/2
International filing date (day/month/year) 15 January 1999 (15.01.99)	**Priority date** (day/month/year) 26 January 1998 (26.01.98)
Applicant CHOSACK, Edna et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

09 August 1999 (09.08.99)

[ ] in a notice effecting later election filed with the International Bureau on:

____

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland** Facsimile No.: (41-22) 740.14.35	Authorized officer Juan Cruz Telephone No.: (41-22) 338.83.38

3739

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as International Preliminary Examining Authority

NOTIFICATION CONCERNING
AMENDMENTS OF THE CLAIMS

(PCT Rule 62 and
Administrative Instructions, Section 417)

Date of mailing (day/month/year) 31 January 2001 (31.01.01)	
International application No. PCT/IL00/00028	International filing date (day/month/year) 16 January 2000 (16.01.00)
Applicant DIUK ENERGY et al	

The International Bureau hereby informs the International Preliminary Examining Authority that no amendments under Article 19 have been received by the International Bureau (Administrative Instructions, Section 417).

TC 3700 MAIL ROOM
FEB 27 2001

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer Athina Nickitas-Etienne Telephone No. (41-22) 338.83.38

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PATENT COOPERATION TREATY

PCT

RECD 07 JUL 2000
WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1220/2	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IL99/00028	International filing date *(day/month/year)* 15/01/1999	Priority date *(day/month/year)* 26/01/1998
International Patent Classification (IPC) or national classification and IPC G09B23/28		
Applicant SIMBIONIX LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 12 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

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TECHNOLOGY CENTER 3700

3. This report contains indications relating to the following items:

   I ☒ Basis of the report
   II ☐ Priority
   III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   IV ☐ Lack of unity of invention
   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   VI ☐ Certain documents cited
   VII ☒ Certain defects in the international application
   VIII ☒ Certain observations on the international application

CORRECTED VERSION

Date of submission of the demand	Date of completion of this report
09/08/1999	06.07.00
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Watson, S Telephone No. +49 89 2399 2840

Form PCT/IPEA/409 (cover sheet) (January 1994)

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-30	as originally filed			

Claims, No.:

1-38	as originally filed			
39-57	as received on	~~22/04/2000~~	with ~~letter of~~ telefax	~~06/04/2000~~ 14/06/2000

Drawings, sheets:

1/25-25/25	as originally filed			

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 55.

because:

☒ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 55 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3, 6-9, 18-22, 25-27, 30, 32-34, 36, 38-49, 51-54, 56-57
	No:	Claims	1, 2, 4, 5, 10-17, 23, 24, 28, 29, 31, 35, 37, 50
Inventive step (IS)	Yes:	Claims	3, 18-20, 25-27, 34, 39-49, 54, 56
	No:	Claims	1-2, 4-17, 21-24, 28-33, 35-38, 50-53, 57
Industrial applicability (IA)	Yes:	Claims	1-54,56-57
	No:	Claims	

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

III Non establishment of opinion

1 No opinion is given as to novelty and inventive step of the subject-matter of claim 55 as this claim does not contain any examinable features.

V Reasoned statement under Rule 66.2(a)(ii)with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO 96 30885 A (Gillio Robert G) 3 October 1996
D2: WO 96 28800 A (High Techsplanations Inc) 19 September 1996
D4: DE 39 37 035 A (Maier Roland Dipl Math; Fueting Frank Dr Med (DE)) 8 May 1991

1. Novelty

1.1 The subject-matter of claim 1 is not new (Article 33(2) PCT).

Document D1 shows a system for performing a simulated medical procedure comprising, a simulated organ (see page 11, lines 14-26, fig. 6); a simulated instrument for performing the simulated medical procedure on said simulated organ (page 6, lines 14-18); a locator for determining a location of said simulated instrument within said simulated organ (page 16, lines 26-32 and page 21, lines 10-12); a visual display for displaying images according to said location of said simulated instrument within said simulated organ for providing visual feedback (fig. 6, 130), such that said images simulate actual visual data received during an actual medical procedure as performed on an actual subject (page 21, lines 12-30), said visual display including:
(i) a mathematical model for modelling said simulated organ according to a corresponding actual organ, said model being divided into a plurality of segments (page 8, lines 14-16, page 25, lines 10-20);
(ii) a loader for selecting at least one of said plurality of segments for display, said at least one of said plurality of segments being selected according to said location of said simulated instrument within said simulated organ (page 21, lines

12-15 and page 22, lines 7-12);

(iii) a controller for selecting a simulated image from said segment according to said location of said simulated instrument (page 25, lines 10-15); and

(iv) a displayer for displaying said simulated image (fig. 6 (130)).

1.2 The subject-matter of claim 28 is not new.

Document D1 shows a method for performing a simulated endoscopic procedure comprising the steps of:

(a) providing a system for performing the simulated endoscopic procedure, comprising:

(i) a simulated gastro-intestinal tract (page 11, lines 22-26);

(ii) a simulated endoscope for performing the simulated endoscopic procedure on said simulated gastro-intestinal tract (page 6, lines 14-22);

(iii) a locator for determining a location of said simulated endoscope within said simulated gastro-intestinal tract (page 16, lines 26-32 and page 21, lines 10-12);

(iv) a visual display for displaying images according to said location of said simulated endoscope within said simulated gastro-intestinal tract, such that said images simulate actual visual data received during an actual medical procedure as performed on an actual subject (page 21, lines 12-30), said visual display including (see point 1.1 above):

(1) a mathematical model for modelling said simulated gastro-intestinal tract, said model being divided into a plurality of segments;

(2) a loader for selecting at least one of said plurality of segments for display, said at least one of said plurality of segments being selected according to said location of said simulated endoscope within said simulated gastro-intestinal tract;

(3) a controller for selecting a simulated image from said segment according to said location of said simulated instrument; and

(4) a displayer for displaying said simulated image according to said controller such that said simulated image is a displayed image.

(b) inserting said simulated endoscope into said simulated gastro-intestinal tract (page 6, lines 20-22);

(c) receiving visual feedback according to said displayed image (page 7, lines 3-8);
(d) receiving tactile feedback according to said location of said endoscope within said gastro-intestinal tract (page 11, lines 1-5).

1.3 The subject-matter of claim 35 is not new. It is known from document D1 to provide a method for teaching a particular skill required for performance of an actual medical procedure to a student, the actual medical procedure being performed with an actual medical instrument on an actual organ with visual feedback (see abstract), the method comprising the steps of:
(a) providing a simulated instrument for simulating said actual medical instrument (see page 6, lines 14-20);
(b) providing a simulated organ for simulating said actual organ (see figure 6);
(c) abstracting a portion of the visual feedback of the actual medical procedure (see page 24, lines 20-21);
(d) providing said portion of the visual feedback for simulating the visual feedback (page 24, line 20 - page 25, line 9); and
(e) manipulating said instrument within said simulated organ by the student according to said portion of the visual feedback, such that a motion of said simulated instrument is the skill taught to the student (abstract and page 25, lines 15-20).

1.4 The subject-matter of claim 50 is not novel. It is known from D1 to provide a method for modelling a local deformation of a simulated organ by a simulated instrument during a performance of a simulated medical procedure on the simulated organ, the simulated organ being modelled by a mathematical model according to a corresponding actual organ, the model being divided into a plurality of segments, the method comprising the steps of:
(a) inserting the simulated instrument into the simulated organ;
(b) determining a location of the simulated instrument relative to a location of the simulated organ; and
(c) if contact is determined to have occurred according to said location of the simulated instrument relative to said location of the simulated organ, determining a deformation to the simulated organ according to the mathematical model (page 14, first paragraph, see also D2, page 17, third

paragraph).

1.5 The subject-matter of claim 2 is not new. It is known from D1 to overlay a simulated image with texture mapping in a system for performing a simulated medical procedure (see page 20, lines 5-10).

1.6 The features of claims 4 and 5, that the texture mapping includes images obtained from performing said actual medical procedure on said actual subject which are obtained by recording and then selecting images, does not render the subject-matter of these claims novel as it is known from D1 (see page 24, line 24-page 25, line 9) to include images obtained from performing the medical procedure.

1.7 The subject-matter of claims 10 and 29 is not new as it is implicit in D1 that the controller selects the simulated image according to at least one previous movement of said instrument within said simulated organ.

1.8 The subject-matter of claims 11 and 12 is not new as it is known from D1 to provide a graphical user interface which can display tutorial information for aid in performing the medical procedure (page 22, lines 9-14).

1.9 The subject-matter of claims 13 and 14 is not new as D1 shows the simulated organ being a gastro-intestinal tract constructed from a semi-flexible smooth material (page 12, line 29-page 13, line 3).

1.10 The additional feature of claim 15, that the simulated instrument is an endoscope which has a sensor for determining the location of the sensor in the gastro-intestinal tract and that the system further comprises a computer for determining visual feedback according to the location of the sensor, is known from D1 (see page 16, lines 18-22), therefore the subject-matter of claim 15 is not novel.

1.11 The subject-matter of claim 16 is not new. D1 discloses a tactile feedback mechanism for providing simulated tactile feedback according to the location of the tip of the endoscope (page 10, line 22-page 11, line 9).

1.12 The subject-matter of claim 17 is not new. Document D1 discloses a tactile feedback mechanism contained within the gastro-intestinal tract comprising a plurality of servo-motors, a piston operated by each of said servo-motors, said piston contacting said semi-flexible material and a controller for controlling said plurality of servo-motors such that a position of said piston is determined by said controller, and such that said position of said piston provides tactile feedback (see page 10, line 28 - page 11, line 9).

1.13 The subject-matter of claims 23 and 24 is not novel as D1 shows the additional features of these claims, namely that there is a handle for holding the endoscope and a tool unit containing a simulated forceps, a channel for receiving forceps in said handle and a tool control unit for detecting a movement of the simulated forceps and being in communication with the computer so that visual and tactile feedback is determined according to movement of the forceps (see page 22, line 26 - page 23, line 23).

1.14 Document D1 discloses the use of video data, MRI data and CAT scan data (see page 24, line 20 - page 25, line 4), therefore the subject-matter of claim 31 is not new.

1.15 The subject-matter of claim 37 is not novel as document D1 shows a gastro-intestinal tract and an endoscope as the simulated organ and instrument.

2. Inventive Step

2.1 The subject-matter of claim 30 is not inventive. Document D1, which is considered to be the closest prior art describes a method for displaying simulated visual data of a medical procedure performed on an actual human organ with an actual medical instrument, the method comprising the steps of:

(a) recording actual data from a performance of an actual medical procedure on a living human patient (see pages 24-25);

(b) abstracting a plurality of individual images from said actual data (implicit);

(c) digitizing said plurality of individual images to form a plurality of digitized

images (implicit as data is stored on computer disc and merged with other forms of data);
(c) selecting at least one of said plurality of digitized images to form a selected digitized image (implicit).

The subject-matter of claim 30 differs from the method of D1 in that it has additional steps of storing the digitized data in a texture mapping database and overlaying this data onto a segmented mathematical model of the human organ to form an image that is then displayed.

The problem to be solved is regarded as being to provide a method for handling the data obtained from the actual data in order to use it in a simulated system. The use of mathematical models of this type and texture mapping is known in the art and it would be obvious for the skilled person to handle the data using the method described in claim 30.

2.2 The subject-matter of claim 57 is not considered to be inventive, the use of splines as mathematical models for three-dimensional structures is generally well known (see for example D2, page 17, last paragraph) and it is obvious to one skilled in the art to use a segmented spline to render an image.

2.3 The subject-matter of claims 6-9, 32 and 33 is not inventive as the features of these claims use obvious mathematical modelling techniques.

2.4 The subject-matter of claim 21 is not inventive as it is an obvious design simplification to make the gastro-intestinal tract from a substantially straight tube.

2.5 It is considered to be an obvious design choice to use virtual reality gloves to provide tactile feedback, therefore the subject-matter of claim 22 is not considered to be inventive.

2.6 The subject-matter of claims 36 and 38 is not inventive. It is an obvious simplification to provide visual feedback with fewer visual details than the visual feedback of the actual medical procedure, with the geometrical shape of the interior being an obvious example of this.

2.7 The subject-matter of claims 51-52 are not inventive as it is known to one skilled in the art of image processing to model the deformation in the manner claimed in these claims.

3.1 The subject-matter of claims 3 and 34 is considered to be novel and inventive as it is not known from the prior art to provide a system/method with the additional feature of simulated random movement of the simulated instrument and the simulated organ.

3.2 The subject-matter of claims 18-20 is also considered to be novel and inventive as such tactile feedback mechanism are not known from nor made obvious by the available prior art.

3.3 The additional features claimed in claims 25-27, regarding the simulated forceps, are also considered to give the subject-matter of these claims novelty and inventiveness.

3.4 The subject-matter of claims 39-46 and 54 is considered to be novel and inventive as it is not known from the available prior art to use a segmented model, where the segments form a linear sequence to model a simulated organ so that the images can be more rapidly displayed.

3.5 The subject-matter of claims 47-49 is also considered to be novel and inventive as it is not known to model an endoscopic loop.

3.6 The force feedback device of claim 56 is not disclosed in the available prior art, the subject-matter of this claim is also considered to be novel and inventive.

VII Certain defects in the international application

1 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art as contained in the documents D1 and D4 are not mentioned in the description, nor are these documents identified therein.

VIII Certain observations on the international application

The claims as a whole do not meet the requirements of Article 6 PCT.
The number of independent claims (1, 28, 30, 35, 39, 47, 50, 54, 55, 56 and 57) makes it difficult to determine the matter for which protection is sought, and places undue burden on others seeking to establish the extent of protection.

In addition, the application does not fulfil the requirement of unity of invention as no special corresponding technical feature exists linking the independent claims.

39. A system for performing a simulated medical procedure, comprising:

(a) a simulated organ;

(b) a simulated instrument for performing the simulated medical procedure on said simulated organ;

(c) a locator for determining a location of said simulated instrument within said simulated organ; and

(d) a visual display for displaying images according to said location of said simulated instrument within said simulated organ for providing visual feedback, such that said images simulate actual visual data received during an actual medical procedure as performed on an actual subject, said visual display including:

   (i) a mathematical model for modeling said simulated organ according to a corresponding actual organ, said model being divided into a plurality of segments, said plurality of segments being arranged in a linear sequence;

   (ii) a loader for selecting at least one of said plurality of segments from said linear sequence for display, said at least one of said plurality of segments being selected according to said location of said simulated instrument within said simulated organ;

   (iii) a controller for selecting a simulated image from said segment according to said location of said simulated instrument, such that said simulated image is more rapidly displayed by being selected from said segment; and

   (iv) a displayer for displaying said simulated image.

40. The system of claim 39, wherein said loader further comprises a rapidly accessed memory for storing said segment.

41. The system of claim 39, wherein said mathematical model features a plurality of polygons defined with respect to a spline, said spline determining a geometry of said mathematical model in three dimensions.

42. The system of claim 41, wherein said simulated instrument is an endoscope featuring an endoscope cable, said endoscope cable forming a loop from a movement of said endoscope in said simulated organ, said loop being modeled according to a mathematical model.

43. The system of claim 42, wherein said mathematical model for said loop features a plurality of polygons defined with respect to a spline.

44. The system of claims 42 or 43, wherein a size of said loop is determined according to a differential between an amount of said endoscope cable within said simulated organ and a length of said simulated organ from an entry point of said endoscope to a current position of said endoscope within said simulated organ.

45. The system of claim 39, wherein said visual displayer further comprises:

(v) a texture mapping database for storing texture mapping data, said texture mapping data including at least a correction for a visual artifact; and

(vi) a texture mapping engine for overlaying said simulated image with said texture mapping data substantially before said simulated image is displayed by said displayer.

46. The system of claim 39, wherein said segment is selected according to a location of said simulated instrument relative to a location of said segment in said linear sequence and within said mathematical model.

47. A method for modeling a loop during a performance of a simulated endoscopic procedure on a simulated organ, the simulated organ being modeled by a mathematical model according to a corresponding actual organ, the model being divided into a plurality of segments, the simulated endoscopic procedure being performed with a simulated endoscope having an endoscope cable, the method comprising the steps of:

(a) inserting the simulated endoscope into the simulated organ;

(b) turning the simulated endoscope within the simulated organ;

(c) modeling a loop of the endoscope cable forming as a result of turning the simulated endoscope within the simulated organ according to a second mathematical model; and

(d) providing at least one of force feedback and visual feedback determined according to second mathematical model of said loop and the mathematical model for the simulated organ.

48. The method of claim 47, wherein said second mathematical model and the mathematical model are each composed of a plurality of polygons defined with respect to a spline, each spline determining a geometry of said second mathematical model and the mathematical model in three dimensions.

49. The method of claim 48, wherein step (c) further comprises the step of determining a size of said loop according to a differential between an amount of the endoscope cable within the simulated organ and a length of the simulated organ from an entry point of the simulated endoscope to a current position of the simulated endoscope within the simulated organ.

50. A method for modeling a local deformation of a simulated organ by a simulated instrument during a performance of a simulated medical procedure on the simulated organ, the simulated organ being modeled by a mathematical model according to a corresponding actual organ, the model being divided into a plurality of segments, the method comprising the steps of:

(a) inserting the simulated instrument into the simulated organ;

(b) determining a location of the simulated instrument relative to a location of the simulated organ; and

(c) if contact is determined to have occurred according to said location of the simulated instrument relative to said location of the simulated organ, determining a deformation to the simulated organ according to the mathematical model.

51. The method of claim 50, wherein step (c) further comprises the step of determining if said deformation includes a deformation of the mathematical model.

52. The method of claim 50, wherein the mathematical model includes a plurality of polygons, the method further comprising the step of:

(d) adding a plurality of polygons to a portion of the mathematical model representing an area of said deformation; and

(e) adjusting a visual representation of said area of said deformation with said plurality of polygons.

53. The method of claim 52, further comprising the steps of:

(f) adding a plurality of polygons to a portion of the mathematical model representing an area of local irregularity in the simulated organ; and

(g) adjusting a visual representation of said area of local irregularity with said plurality of polygons.

54. A computer readable medium encoded with a method for performing a simulated medical procedure, the simulated medical procedure being performed with a simulated instrument on a simulated organ, the steps of the method being performed by a data processor, the method comprising the steps of:

(a) constructing a mathematical model for simulating the simulated organ, said mathematical model featuring a plurality of segments arranged in a linear sequence;

(b) determining a location of the simulated instrument in the simulated organ;

(c) selecting a segment of said mathematical model according to said location of the simulated instrument;

(d) selecting a simulated image from said segment according to said location of the simulated instrument; and

(e) displaying said simulated image.

55. A device substantially as described in Figures 1-9E and in the text of the specification.

56. A device for providing force feedback for simulating a medical procedure performed with a simulated instrument, the device comprising:

(a) at least one inflatable ring for being contacted by the simulated instrument and for providing the force feedback on the simulated instrument;

(b) at least one tube connected to said at least one inflatable ring for alternately inflating and deflating said at least one inflatable ring; and

(c) a pump connected to said at least one tube for alternately pumping air into, and suctioning air from, said at least one inflatable ring for controlling an amount of the force feedback on the simulated instrument.

57 A method for rendering a plurality of images according to a three-dimensional structure, the steps of the method being performed by a data processor, the method comprising the steps of:

(a) providing a mathematical model of the three-dimensional structure, said mathematical model including a spline;

(b) dividing said spline into a plurality of segments, each segment including at least one image;

(c) selecting a segment for rendering an image; and

(d) rendering said image.

56. A device for providing force feedback for simulating a medical procedure performed with a simulated instrument, the device comprising:

(a) at least one inflatable ring for being contacted by the simulated instrument and for providing the force feedback on the simulated instrument;

(b) at least one tube connected to said at least one inflatable ring for alternately inflating and deflating said at least one inflatable ring; and

(c) a pump connected to said at least one tube for alternately pumping air into, and suctioning air from, said at least one inflatable ring for controlling an amount of the force feedback on the simulated instrument.

57 A method for rendering a plurality of images according to a three-dimensional structure, the steps of the method being performed by a data processor, the method comprising the steps of:

(a) providing a mathematical model of the three-dimensional structure, said mathematical model including a spline;

(b) dividing said spline into a plurality of segments, each segment including at least one image;

(c) selecting a segment for rendering an image; and

(d) rendering said image.

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only
International Application No.
International Filing Date
Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) 1220/2

Box No. I TITLE OF INVENTION

ENDOSCOPIC TUTORIAL SYSTEM

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

SIMBIONIX LTD.
2/A Katzir Street
Ramat Gan 52656
Israel

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State *(that is, country)* of nationality: IL

State *(that is, country)* of residence: IL

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

CHOSACK, Edna
9 Zahal Street
Kiryat Ono 55451
Israel

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: IL

State *(that is, country)* of residence: IL

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

FRIEDMAN, Mark M.
Beit Samueloff
7 Haomanim Street
Tel Aviv 67897
Israel

Telephone No.
972-3-5625553

Facsimile No.
972-3-5625554

Teleprinter No.

☐ **Adress for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANTS AND/OR (FURTHER) INVENTORS

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BARKAY, David
3 Hermann Cohen Street
Tel Aviv
Israel

This person is:

- [ ] applicant only
- [x] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: IL

State *(that is, country)* of residence: IL

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [x] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BRONSTEIN, Ran
23 Almogan Street
Modiin
Israel

This person is:

- [ ] applicant only
- [x] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: IL

State *(that is, country)* of residence: IL

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [x] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:

- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:

- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

- [ ] Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

☒ AP **ARIPO Patent: GH** Ghana, **GM** Gambia, **KE** Kenya, **LS** Lesotho, **MW** Malawi, **SD** Sudan, **SZ** Swaziland, **UG** Uganda, **ZW** Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT

☒ EA **Eurasian Patent: AM** Armenia, **AZ** Azerbaijan, **BY** Belarus, **KG** Kyrgyzstan, **KZ** Kazakhstan, **MD** Republic of Moldova, **RU** Russian Federation, **TJ** Tajikistan, **TM** Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ EP **European Patent: AT** Austria, **BE** Belgium, **CH and LI** Switzerland and Liechtenstein, **CY** Cyprus, **DE** Germany, **DK** Denmark, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☒ OA **OAPI Patent: BF** Burkina Faso, **BJ** Benin, **CF** Central African Republic, **CG** Congo, **CI** Côte d'Ivoire, **CM** Cameroon, **GA** Gabon, **GN** Guinea, **ML** Mali, **MR** Mauritania, **NE** Niger, **SN** Senegal, **TD** Chad, **TG** Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* . . . .

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- ☒ **AL** Albania
- ☒ **AM** Armenia
- ☒ **AT** Austria
- ☒ **AU** Australia
- ☒ **AZ** Azerbaijan
- ☒ **BA** Bosnia and Herzegovina
- ☒ **BB** Barbados
- ☒ **BG** Bulgaria
- ☒ **BR** Brazil
- ☒ **BY** Belarus
- ☒ **CA** Canada
- ☒ **CH and LI** Switzerland and Liechtenstein
- ☒ **CN** China
- ☒ **CU** Cuba
- ☒ **CZ** Czech Republic
- ☒ **DE** Germany
- ☒ **DK** Denmark
- ☒ **EE** Estonia
- ☒ **ES** Spain
- ☒ **FI** Finland
- ☒ **GB** United Kingdom
- ☒ **GE** Georgia
- ☒ **GH** Ghana
- ☒ **GM** Gambia
- ☐ **GW** Guinea-Bissau
- ☒ **HR** Croatia
- ☒ **HU** Hungary
- ☒ **ID** Indonesia
- ☒ **IL** Israel
- ☒ **IS** Iceland
- ☒ **JP** Japan
- ☒ **KE** Kenya
- ☒ **KG** Kyrgyzstan
- ☒ **KP** Democratic People's Republic of Korea
- ☒ **KR** Republic of Korea
- ☒ **KZ** Kazakhstan
- ☒ **LC** Saint Lucia
- ☒ **LK** Sri Lanka
- ☒ **LR** Liberia
- ☒ **LS** Lesotho
- ☒ **LT** Lithuania
- ☒ **LU** Luxembourg
- ☒ **LV** Latvia
- ☒ **MD** Republic of Moldova
- ☒ **MG** Madagascar
- ☒ **MK** The former Yugoslav Republic of Macedonia
- ☒ **MN** Mongolia
- ☒ **MW** Malawi
- ☒ **MX** Mexico
- ☒ **NO** Norway
- ☒ **NZ** New Zealand
- ☒ **PL** Poland
- ☒ **PT** Portugal
- ☒ **RO** Romania
- ☒ **RU** Russian Federation
- ☒ **SD** Sudan
- ☒ **SE** Sweden
- ☒ **SG** Singapore
- ☒ **SI** Slovenia
- ☒ **SK** Slovakia
- ☒ **SL** Sierra Leone
- ☒ **TJ** Tajikistan
- ☒ **TM** Turkmenistan
- ☒ **TR** Turkey
- ☒ **TT** Trinidad and Tobago
- ☒ **UA** Ukraine
- ☒ **UG** Uganda
- ☒ **US** United States of America
- ☒ **UZ** Uzbekistan
- ☒ **VN** Viet Nam
- ☒ **YU** Yugoslavia
- ☒ **ZW** Zimbabwe

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- ☒ Grenada
- ☐ . . . .

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application *(day/month/year)*	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) 26 JAN 1998 (26.01.98)	123073	IL		
item (2)				
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): (1)

* *Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):*

ISA / EP

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*

Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets**:

request	: 4
description (excluding sequence listing part)	: 30
claims	: 8
abstract	: 1
drawings	: 25
sequence listing part of description	:
Total number of sheets	: 68

This international application is **accompanied by** the item(s) marked below:

1. ☒ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☐ other *(specify)*:

Figure of the drawings which should accompany the abstract:

Language of filing of the international application: ENGLISH

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

FRIEDMAN, Mark M.
Agent

For receiving Office use only

1. Date of actual receipt of the purported international application:
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA /
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

This sheet is not part of and does not count as a sheet of the international application.

PCT

FEE CALCULATION SHEET

Annex to the Request

For receiving Office use only

International application No.

Date stamp of the receiving Office

Applicant's or agent's file reference 1220/2

Applicant

SIMBIONIX LTD.

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE . . . . ILS 425 **T**
2. SEARCH FEE . . . . USD 1250 **S**

   International search to be carried out by EP

   (If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)
3. INTERNATIONAL FEE

   Basic Fee

   The international application contains 68 sheets.

   first 30 sheets . . . . USD 455 b_1

   38 (remaining sheets) x 10 (additional amount) = USD 380 b_2

   Add amounts entered at b_1 and b_2 and enter total at B . . . . USD 835 **B**

   Designation Fees

   The international application contains all designations.

   10 (number of designation fees payable *(maximum 11)*) x 105 (amount of designation fee) = USD 1050 **D**

   Add amounts entered at B and D and enter total at I . . . . USD 1885 **I**

   (Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)
4. FEE FOR PRIORITY DOCUMENT . . . . ILS 35 **P**
5. TOTAL FEES PAYABLE

   Add amounts entered at T, S, I and P, and enter total in the TOTAL box . . ILS 460 / USD 3135

   TOTAL

☐ The designation fees are not paid at this time.

MODE OF PAYMENT

☐ authorization to charge deposit account (see below) ☐ bank draft ☐ coupons

☐ cheque ☒ cash ☐ other *(specify)*:

☐ postal money order ☐ revenue stamps

DEPOSIT ACCOUNT AUTHORIZATION *(this mode of payment may not be available at all receiving Offices)*

The RO/ ______

☐ is hereby authorized to charge the total fees indicated above to my deposit account.

☐ is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

☐ is hereby authorized to charge the fee for preparation and transmittal of the priority document to the International Bureau of WIPO to my deposit account.

Deposit Account Number | Date *(day/month/year)* | Signature

PATENT COOPERATION TREATY

PCT

REC'D 10 MAY 2000

WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1220/2	**FOR FURTHER ACTION** See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IL99/00028	International filing date *(day/month/year)* 15/01/1999	Priority date *(day/month/year)* 26/01/1998
International Patent Classification (IPC) or national classification and IPC G09B23/28		
Applicant SIMBIONIX LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report
   II ☐ Priority
   III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   IV ☐ Lack of unity of invention
   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   VI ☐ Certain documents cited
   VII ☒ Certain defects in the international application
   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09/08/1999	09.05.2000
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Watson, S Telephone No. +49 89 2399 2840

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-30 as originally filed

Claims, No.:

1-38 as originally filed

Drawings, sheets:

1/25-25/25 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-9, 17-27, 30-34, 36, 38
	No:	Claims	1, 10-16, 28-29, 35, 37
Inventive step (IS)	Yes:	Claims	3, 18-20, 25-27, 34
	No:	Claims	1, 2, 4-17, 21-24, 28-33, 35-38
Industrial applicability (IA)	Yes:	Claims	1-38
	No:	Claims	

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT - SEPARATE SHEET International application No. PCT/IL99/00028

V **Reasoned statement under Rule 66.2(a)(ii)with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: WO 96 30885 A (Gillio Robert G) 3 October 1996

D4: DE 39 37 035 A (Maier Roland Dipl Math; Fueting Frank Dr Med (DE)) 8 May 1991

1. <u>Novelty</u>

1.1 The subject-matter of claim 1 is not new (Article 33(2) PCT).

Document D4 shows a system for performing a simulated medical procedure comprising, a simulated organ (see col. 2, lines 19-26); a simulated instrument for performing the simulated medical procedure on said simulated organ (col. 1, lines 59-63); a locator for determining a location of said simulated instrument within said simulated organ (col. 1, line 63-col. 2, line 1); a visual display for displaying images according to said location of said simulated instrument within said simulated organ for providing visual feedback (col. 2, lines 11-18 and fig 1), such that said images simulate actual visual data received during an actual medical procedure as performed on an actual subject (col. 2, lines 7-13), said visual display including:

(i) a mathematical model for modelling said simulated organ according to a corresponding actual organ, said model being divided into a plurality of segments (although D4 does not explicitly mention a segmented mathematical model, it is implicit that some form of segmented mathematical model must be used by the software in order to determine which picture should be displayed in accordance with the location of the end of the simulated medical instrument);

(ii) a loader for selecting at least one of said plurality of segments for display, said at least one of said plurality of segments being selected according to said location of said simulated instrument within said simulated organ (col. 2, lines 13-18);

(iii) a controller for selecting a simulated image from said segment according to said location of said simulated instrument (col. 2, lines 39-44); and

(iv) a displayer for displaying said simulated image (col 2, lines 14-16).

1.8 The subject-matter of claim 16 is not new. D4 discloses a tactile feedback mechanism for providing simulated tactile feedback according to the location of the tip of the endoscope (col. 2, lines 27-35).

1.9 The subject-matter of claim 37 is not novel as document D1 shows a gastro-intestinal tract and an endoscope as the simulated organ and instrument.

2. <u>Inventive Step</u>

2.1 The subject-matter of claim 30 is not inventive. Document D1, which is considered to be the closest prior art describes a method for displaying simulated visual data of a medical procedure performed on an actual human organ with an actual medical instrument, the method comprising the steps of:

(a) recording actual data from a performance of an actual medical procedure on a living human patient (see pages 24-25);

(b) abstracting a plurality of individual images from said actual data (implicit);

(c) digitizing said plurality of individual images to form a plurality of digitized images (implicit as data is stored on computer disc and merged with other forms of data);

(c) selecting at least one of said plurality of digitized images to form a selected digitized image (implicit).

The subject-matter of claim 30 differs from the method of D1 in that it has additional steps of storing the digitized data in a texture mapping database and overlaying this data onto a segmented mathematical model of the human organ to form an image that is then displayed.

The problem to be solved is regarded as being to provide a method for handling the data obtained from the actual data in order to use it in a simulated system. The use of mathematical models of this type and texture mapping is known in the art and it would be obvious for the skilled person to handle the data using the method described in claim 30.

2.2 The subject-matter of claim 2 is not inventive. It is generally known to overlay a

simulated image with texture mapping in a system for performing a simulated medical procedure (see for example D1, page 20, lines 5-10).

2.3 The features of claims 4 and 5, that the texture mapping includes images obtained from performing said actual medical procedure on said actual subject which are obtained by recording and then selecting images, does not render the subject-matter of these claims inventive as it is known from D1 (see page 24, line 24-page 25, line 9) to include images obtained from performing the medical procedure.

2.4 The subject-matter of claims 6-9, 32 and 33 is not inventive as the features of these claims use obvious mathematical modelling techniques.

2.5 The subject-matter of claim 17 is not inventive. Document D1 discloses a tactile feedback mechanism contained within the gastro-intestinal tract comprising a plurality of servo-motors, a piston operated by each of said servo-motors, said piston contacting said semi-flexible material and a controller for controlling said plurality of servo-motors such that a position of said piston is determined by said controller, and such that said position of said piston provides tactile feedback (see page 10, line 28 - page 11, line 9).

2.6 The subject-matter of claim 21 is not inventive as it is an obvious design simplification to make the gastro-intestinal tract from a substantially straight tube.

2.7 It is considered to be an obvious design choice to use virtual reality gloves to provide tactile feedback, therefore the subject-matter of claim 22 is not considered to be inventive.

2.8 The subject-matter of claims 23 and 24 is not inventive as D1 shows the additional features of these claims, namely that there is a handle for holding the endoscope and a tool unit containing a simulated forceps, a channel for receiving forceps in said handle and a tool control unit for detecting a movement of the simulated forceps and being in communication with the computer so that visual and tactile feedback is determined according to movement of the forceps (see page 22, line 26 - page 23, line 23).

2.9 Document D1 discloses the use of video data, MRI data and CAT scan data (see page 24, line 20 - page 25, line 4), therefore the subject-matter of claim 31 is not inventive.

2.9 The subject-matter of claims 36 and 38 is not inventive. It is an obvious simplification to provide visual feedback with fewer visual details than the visual feedback of the actual medical procedure, with the geometrical shape of the interior being an obvious example of this.

3.1 The subject-matter of claims 3 and 34 is considered to be novel and inventive as it is not known from the prior art to provide a system/method with the additional feature of simulated random movement of the simulated instrument and the simulated organ.

3.2 The subject-matter of claims 18-20 is also considered to be novel and inventive as such tactile feedback mechanism are not known from nor made obvious by the available prior art.

3.3 The additional features claimed in claims 25-27, regarding the simulated forceps, are also considered to give the subject-matter of these claims novelty and inventiveness.

VII Certain defects in the international application

1 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art as contained in the documents D1 and D4 are not mentioned in the description, nor are these documents identified therein.

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 18942 A (LIVEZEY DARRELL L ;MOORE ROBERT S (US); HARTHAN LEWIS JOHN III (US) 20 June 1996 see page 14, line 14 - page 14, line 20; claims 1-20; figures 1-4 ---	1-5,15, 16,18, 19,28
A	DE 39 37 035 A (MAIER ROLAND DIPL MATH ;FUETING FRANK DR MED (DE)) 8 May 1991 see the whole document ---	1,14-16, 28
A	DE 38 34 553 A (KUBIN SIEGFRIED DR MED) 12 April 1990 see the whole document -----	1,13

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL 99/00028

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9630885 A	03-10-1996	US 5882206 A	16-03-1999
		AU 5380396 A	16-10-1996
		US 5791908 A	11-08-1998
		US 5755577 A	26-05-1998
		US 5800177 A	01-09-1998
		US 5704791 A	06-01-1998
		US 5800178 A	01-09-1998
WO 9628800 A	19-09-1996	AU 5025396 A	02-10-1996
		CA 2144505 A	11-09-1996
WO 9618942 A	20-06-1996	US 5771181 A	23-06-1998
		AU 4520196 A	03-07-1996
DE 3937035 A	08-05-1991	WO 9106935 A	16-05-1991
DE 3834553 A	12-04-1990	NONE	

ATENT COOPERATION TREAT

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 1220/2	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IL 99/ 00028	International filing date *(day/month/year)* 15/01/1999	(Earliest) Priority Date *(day/month/year)* 26/01/1998
Applicant SIMBIONIX LTD. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 5A

   [ ] as suggested by the applicant.

   [X] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 99/00028

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G09B23/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G09B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 30885 A (GILLIO ROBERT G) 3 October 1996 see page 11, line 22 - page 14, line 11 see page 18, line 28 - page 27, line 19; claims 1-48 ---	1,2,4,5, 13, 15-18, 22,23, 28-31, 35,37
A	WO 96 28800 A (HIGH TECHSPLANATIONS INC) 19 September 1996 see the whole document --- -/--	1-12,15, 16,18, 25,28, 30-33

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 May 1999	19/05/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Gorun, M

1

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 18942 A (LIVEZEY DARRELL L ;MOORE ROBERT S (US); HARTHAN LEWIS JOHN III (US) 20 June 1996 see page 14, line 14 - page 14, line 20; claims 1-20; figures 1-4 ---	1-5,15, 16,18, 19,28
A	DE 39 37 035 A (MAIER ROLAND DIPL MATH ;FUETING FRANK DR MED (DE)) 8 May 1991 see the whole document ---	1,14-16, 28
A	DE 38 34 553 A (KUBIN SIEGFRIED DR MED) 12 April 1990 see the whole document -----	1,13

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL 99/00028

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9630885 A	03-10-1996	US 5882206 A	16-03-1999
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WO 9628800 A	19-09-1996	AU 5025396 A	02-10-1996
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		AU 4520196 A	03-07-1996
DE 3937035 A	08-05-1991	WO 9106935 A	16-05-1991
DE 3834553 A	12-04-1990	NONE	

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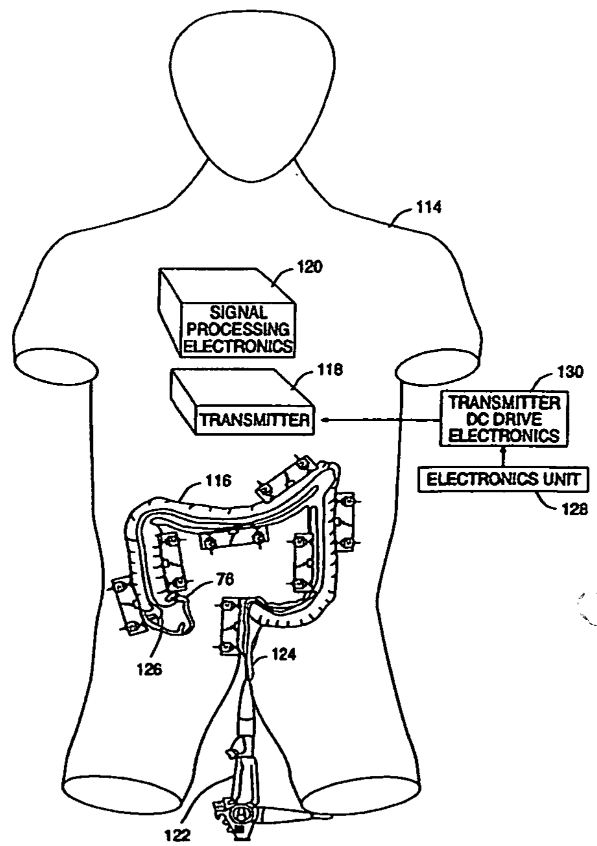
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: ENDOSCOPIC TUTORIAL SYSTEM

(57) Abstract

A system for simulating a medical procedure performed on a subject, featuring: (a) a simulated organ; (b) a simulated instrument for performing the medical procedure on the simulated organ; (c) a locator for determining a location of the simulated instrument within the simulated organ; and (d) a visual display for displaying images from the medical procedure, such that the images simulate visual data received during the medical procedure as performed on an actual subject, the visual display including: (i) a three-dimensional model of the simulated organ, the model being divided into a plurality of segments; (ii) a loader for selecting at least one of the plurality of segments for display, the at least one of the plurality of segments being selected according to the location of the simulated instrument within the simulated organ; (iii) a controller for selecting each image from the selected segment according to the location of the simulated instrument; and (iv) a displayer for displaying the image according to the controller.



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ENDOSCOPIC TUTORIAL SYSTEM

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to a system and method for teaching and training students in medical procedures, and in particular to a system and method for training students in the procedure of endoscopy.

Endoscopy, and in particular flexible gastro-endoscopy, are examples of minimally invasive medical procedures. Flexible gastro-endoscopy is an important medical tool for both surgical and diagnostic procedures in the gastro-intestinal tract. Essentially, gastro-endoscopy is performed by inserting an endoscope, which is a flexible tube, into the gastro-intestinal tract, either through the mouth or the rectum of the subject. The tube is manipulated by a trained physician through specialized controls. The end of the tube which is inserted into the subject contains a camera and one or more surgical tools, such as a clipper for removing tissue samples from the gastro-intestinal tract. The physician must maneuver the tube according to images of the gastro-intestinal tract received from the camera and displayed on a video screen. The lack of direct visual feedback from the gastro-intestinal tract is one factor which renders endoscopy a complex and difficult procedure to master. Such lack of feedback also increases the difficulty of hand-eye coordination and correct manipulation of the endoscopic device. Thus, flexible gastro-endoscopy is a difficult procedure to both perform and to learn.

Currently, students are taught to perform flexible gastro-endoscopy according to the traditional model for medical education, in which students observe and assist more experienced physicians. Unfortunately, such observation alone cannot provide the necessary training for such complicated medical procedures. Students may also perform procedures on animals and human cadavers, neither of which replicates the visual and tactile sensations of a live human patient. Thus, traditional medical training is not adequate for modern technologically complex medical procedures.

In an attempt to provide more realistic medical training for such procedures, simulation devices have been developed which attempt to replicate the tactile sensations and/or visual feedback for these procedures, in order to provide improved medical training without endangering human patients. An example of such a simulation device is disclosed in U.S. Patent No. 5,403,191, in which the disclosed device is a box containing simulated human organs. Various surgical laparoscopic procedures can be performed on the simulated organs.

Visual feedback is provided by a system of mirrors. However, the system of both visual and tactile feedback is primitive in this device, and does not provide a true representation of the visual and tactile sensations which would accompany such surgical procedures in a human patient. Furthermore, the box itself is not a realistic representation of the three-dimensional structure of a human patient. Thus, the disclosed device is lacking in many important aspects and fails to meet the needs of a medical simulation device.

Attempts to provide a more realistic experience from a medical simulation devices are disclosed in PCT Patent Application Nos. WO 96/16389 and WO 95/02233. Both of these applications disclose a device for providing a simulation of the surgical procedure of laparoscopy. Both devices include a mannequin in the shape of a human torso, with various points at which simulated surgical instruments are placed. However, the devices are limited in that the positions of the simulated surgical instruments are predetermined, which is not a realistic scenario. Furthermore, the visual feedback is based upon a stream of video images taken from actual surgical procedures. However, such simple rendering of video images would result in inaccurate or unrealistic images as portions of the video data would need to be removed for greater processing speed. Alternatively, the video processing would consume such massive amounts of computational time and resources that the entire system would fail to respond in a realistic time period to the actions of the student. At the very minimum, a dedicated graphics workstation would be required, rather than a personal computer (PC). Thus, neither reference teaches or discloses adequate visual processing for real time visual feedback of the simulated medical procedure.

Similarly, U.S. Patent No. 4,907,973 discloses a device for simulating the medical procedure of flexible gastro-endoscopy. The disclosed device also suffers from the deficiencies of the above-referenced prior art devices, in that the visual feedback system is based upon rendering of video data taken from actual endoscopic procedures. As noted previously, displaying such data would either require massive computational resources, or else would simply require too much time for a realistic visual feedback response. Thus, the disclosed device also suffers from the deficiencies of the prior art.

A truly useful and efficient medical simulation device for minimally invasive therapeutic procedures such as endoscopy would give real time, accurate and realistic visual feedback of the procedure, and would also give realistic tactile feedback, so that the visual and tactile systems would be accurately linked for the simulation as for an actual medical

procedure. Unfortunately, such a simulation device is not currently taught or provided by the prior art.

There is therefore a need for, and it would be useful to have, a method and a system to simulate a minimally invasive medical procedure such as endoscopy, which would provide accurate, linked visual and tactile feedback to the student and which would serve as a training resource for all aspects of the procedure.

SUMMARY OF THE INVENTION

The present invention includes a method and a system to simulate the minimally invasive medical procedure of endoscopy, particularly of flexible gastro-endoscopy. The system is designed to simulate the actual medical procedure of endoscopy as closely as possible by providing both a simulated medical instrument, and tactile and visual feedback as the simulated procedure is performed on the simulated patient.

According to the present invention, there is provided a system for performing a simulated medical procedure, comprising: (a) a simulated organ; (b) a simulated instrument for performing the simulated medical procedure on the simulated organ; (c) a locator for determining a location of the simulated instrument within the simulated organ; and (d) a visual display for displaying images according to the location of the simulated instrument within the simulated organ for providing visual feedback, such that the images simulate actual visual data received during an actual medical procedure as performed on an actual subject, the visual display including: (i) a mathematical model for modeling the simulated organ according to a corresponding actual organ, the model being divided into a plurality of segments; (ii) a loader for selecting at least one of the plurality of segments for display, the at least one of the plurality of segments being selected according to the location of the simulated instrument within the simulated organ; (iii) a controller for selecting a simulated image from the segment according to the location of the simulated instrument; and (iv) a displayer for displaying the simulated image.

Preferably, the visual displayer further comprises: (v) a texture mapping database for storing texture mapping data; and (vi) a texture mapping engine for overlaying the simulated image with the texture mapping data substantially before the simulated image is displayed by the displayer. More preferably, the texture mapping is animation of random movement of the simulated instrument and random movement of the simulated organ.

Also preferably, the texture mapping includes images obtained from performing the actual medical procedure on the actual subject.

More preferably, the images are obtained by first recording the visual data during the performance and then selecting the images from the recorded visual data.

According to a preferred embodiment of the present invention, the mathematical model features a plurality of polygons constructed according to a spline, the spline determining a geometry of the mathematical model in three dimensions. Preferably, a deformation in the mathematical model corresponding to a deformation in the simulated organ is determined by altering the spline. More preferably, the deformation in the simulated organ is a local deformation, the local deformation of the simulated organ being determined according to the mathematical model by adding polygons to a portion of the mathematical model, such that the portion of the mathematical model is deformed to produce the local deformation. Most preferably, the mathematical model is constructed from the spline by modeling the simulated organ as a straight line and altering the spline until the mathematical model fits the corresponding actual organ. Also most preferably, the controller selects the simulated image according to at least one previous movement of the simulated instrument within the simulated organ.

According to other preferred embodiments of the present invention, the displayer further displays a graphical user interface. Preferably, the graphical user interface displays tutorial information for aid in performing the medical procedure.

According to still other preferred embodiments of the present invention, the simulated organ is a gastro-intestinal tract. Preferably, the gastro-intestinal tract is constructed from a semi-flexible, smooth material. Also preferably, the simulated instrument is an endoscope, the endoscope featuring a sensor for determining a location of the sensor in the gastro-intestinal tract, the system further comprising: (e) a computer for determining the visual feedback according to the location of the sensor.

Preferably, the system also features a tactile feedback mechanism for providing simulated tactile feedback according to the location of the tip of the endoscope.

According to one embodiment of the tactile feedback mechanism, the tactile feedback mechanism is contained in the gastro-intestinal tract, and the gastro-intestinal tract further comprises: (i) a plurality of servo-motors; (ii) a piston operated by each of the plurality of servo-motors, the piston contacting the semi-flexible material; and (iii) a controller for

controlling the plurality of servo-motors, such that a position of the piston is determined by the controller, and such that the position of the piston provides the tactile feedback.

Alternatively, the tactile feedback mechanism is located in the endoscope, and the endoscope further comprises: (i) a guiding sleeve connected to the tip of the endoscope; (ii) at least one ball bearing attached to the guiding sleeve for rolling along an inner surface of the gastro-intestinal tract; (iii) at least one linear motor attached to the guiding sleeve; (iv) a piston operated by the linear motor, the piston contacting the inner surface of the gastro-intestinal tract; and (v) a controller for controlling the linear motor, such that a position of the piston is determined by the controller, and such that the position of the piston provides the tactile feedback.

Also alternatively, the tactile feedback mechanism features: (i) a plurality of rings surrounding the endoscope, each ring having a different radius, at least a first ring featuring a radius greater than a radius of the endoscope and at least a second ring featuring a radius less than the radius of the endoscope, the radius of each of the plurality of rings being controlled according to a degree of inflation with air of each of the plurality of rings, the radius of the rings determining movement of the endoscope; (ii) an air pump for pumping air into the plurality of rings; (iii) at least one tube for connecting the air pump to the plurality of rings; and (iv) an air pump controller for determining the degree of inflation with air of the plurality of rings by controlling the air pump.

Preferably, the at least one tube is two tubes, a first tube for pumping air into the plurality of rings and a second tube for suctioning air from the plurality of rings, and the air pump pumps air into the plurality of rings and sucks air from the plurality of rings, such that the degree of inflation with air of the plurality of rings is determined by alternately pumping air into, and suctioning air from, the plurality of rings.

Also preferably, the gastro-intestinal tract is a substantially straight tube, such that the tactile feedback and the visual feedback are substantially independent of a geometrical shape of the gastro-intestinal tract. Preferably, the tactile feedback mechanism is operated according to tactile feedback obtained during the performance of the medical procedure on an actual subject, the tactile feedback being obtained through virtual reality gloves.

According to other preferred embodiments of the system of the present invention, the endoscope further features a handle for holding the endoscope and a tool unit, the tool unit comprising: (i) a simulated tool; (ii) a channel for receiving the simulated master of an actual

tool, such as forceps or snare, the channel being located in the handle; (iii) a tool control unit for detecting a movement of the simulated tool, the tool control unit being located in the channel and the tool control unit being in communication with the computer, such that the computer determines the visual feedback and the tactile feedback according to the movement of the simulated tool.

Preferably, the tool control unit detects a location of the simulated tool within the gastro-intestinal tract for providing visual feedback.

More preferably, the tool control unit additionally detects a roll of the simulated tool for providing visual feedback.

According to one embodiment of the tool control unit, the tool control unit further comprises: (1) a light source for producing light, the light source being located in the channel; (2) a light wheel for alternately blocking and unblocking the light according to the movement of the simulated tool; and (3) a light detector for detecting the light, such that the computer determines a movement of the simulated tool according to the light detector.

According to another embodiment of the present invention, there is provided a method for performing a simulated endoscopic procedure, comprising the steps of: (a) providing a system for performing the simulated endoscopic procedure, comprising: (i) a simulated gastro-intestinal tract; (ii) a simulated endoscope for performing the simulated endoscopic procedure on the simulated gastro-intestinal tract; (iii) a locator for determining a location of the simulated endoscope within the simulated gastro-intestinal tract; and (iv) a visual display for displaying images according to the simulated endoscope within the simulated gastro-intestinal tract, such that the images simulate visual data received during an actual medical procedure as performed on an actual subject, the visual display including: (1) a three-dimensional mathematical model of the simulated gastro-intestinal tract, the model being divided into a plurality of segments; (2) a loader for selecting at least one of the plurality of segments for display, the at least one of the plurality of segments being selected according to the location of the simulated endoscope within the simulated gastro-intestinal tract; (3) a controller for selecting a simulated image from the segment according to the location of the simulated instrument; and (4) a displayer for displaying the simulated image according to the controller, such that the simulated image is a displayed image; (b) inserting the simulated endoscope into the simulated gastro-intestinal tract; (c) receiving visual feedback according to the displayed image; and (d) receiving tactile feedback according to the location of the endoscope within the

gastro-intestinal tract.

Preferably, the displayed image is determined according to at least one previous movement of the simulated endoscope within the simulated gastro-intestinal tract.

According to yet another embodiment of the present invention, there is provided a method for displaying simulated visual data of a medical procedure performed on an actual human organ with an actual medical instrument, the method comprising the steps of: (a) recording actual data from a performance of an actual medical procedure on a living human patient; (b) abstracting a plurality of individual images from the actual data; (c) digitizing the plurality of individual images to form a plurality of digitized images; (d) selecting at least one of the plurality of digitized images to form a selected digitized image; (e) storing the selected digitized image as texture mapping data in a texture mapping database; (f) providing a mathematical model of the actual human organ, the model being divided into a plurality of segments; (g) selecting one of the plurality of segments from the model for display; (h) overlaying the texture mapping data from the texture mapping database onto the segment of the model to form at least one resultant image; and (i) displaying the resultant image.

Preferably, the actual data from the performance of the actual medical procedure is selected from the group consisting of video data, MRI (magnetic resonance imaging) data and CAT (computer assisted tomography) scan data.

More preferably, step (f) further comprises the steps of: (i) modeling the actual human organ as a plurality of polygons according to a spline; (ii) mapping the spline to the actual human organ according to three-dimensional coordinates; (iii) altering the spline such that the spline fits the actual data.

Most preferably, the texture mapping data further include animation. Also most preferably, the animation includes random movement of the actual medical instrument and random movement of the actual human organ.

According to still another embodiment of the present invention, there is provided a method for teaching a particular skill required for performance of an actual medical procedure to a student, the actual medical procedure being performed with an actual medical instrument on an actual organ with visual feedback, the method comprising the steps of: (a) providing a simulated instrument for simulating the actual medical instrument; (b) providing a simulated organ for simulating the actual organ; (c) abstracting a portion of the visual feedback of the actual medical procedure; (d) providing the portion of the visual feedback for simulating the

visual feedback; and (e) manipulating the simulated instrument within the simulated organ by the student according to the portion of the visual feedback, such that a motion of the simulated instrument is the skill taught to the student.

Preferably, the portion of the visual feedback includes substantially fewer visual details than the visual feedback of the actual medical procedure.

More preferably, the simulated organ is a simulation of a gastro-intestinal tract, and the simulated instrument is a simulation of an endoscope.

Most preferably, the portion of the visual feedback includes only a geometrical shape of an interior of the gastro-intestinal tract.

The method of the present invention for preparing a model of the simulated organ, and for rendering the visual feedback of the simulated organ during the simulated medical procedure, can be described as a plurality of instructions being performed by a data processor. As such, these instructions can be implemented in hardware, software or firmware, or a combination thereof. As software, the steps of the method of the present invention could be implemented in substantially any suitable programming language which could easily be selected by one of ordinary skill in the art, including but not limited to, C and C++.

Hereinafter, the term "simulated medical procedure" refers to the simulation of the medical procedure as performed through the system and method of the present invention. Hereinafter, the term "actual medical procedure" refers to the performance of the medical procedure on an actual, living human patient with an actual endoscope, such that the medical procedure is "real" rather than "simulated". Hereinafter, the term "corresponding actual organ" refers to the "real" organ of a human being or other mammal which is being simulated by the simulated organ of the present invention.

Hereinafter, the term "endoscopy" includes, but is not limited to, the procedure of flexible gastro-endoscopy, as previously described, and medical diagnostic and surgical procedures in which an endoscope is inserted into the mouth or the rectum of the subject for manipulation within the gastro-intestinal tract of the subject. Hereinafter, the term "subject" refers to the human or lower mammal upon which the method and system of the present invention are performed or operated. Hereinafter, the term "student" refers to any human using the system of the present invention, being trained according to the present invention or being taught according to the present invention including, but not limited to, students attending medical school or a university, a medical doctor, a trained gastro-enterologist or

other trained medical specialist.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, aspects and advantages will be better understood from the following detailed description of a preferred embodiment of the invention with reference to the drawings, wherein:

FIG. 1 is an exemplary illustration of the system for medical simulation according to the present invention;

FIG. 2 is an exemplary illustration of a screen display according to the present invention;

FIG. 3A is a flowchart of an exemplary method according to the present invention for preparation of the visual model of the simulated organ and rendering of visual feedback and FIG. 3B is a schematic block diagram of an exemplary visual processing and display system according to the present invention;

FIG. 4 is a schematic block diagram of an exemplary tutorial system according to the present invention;

FIGS. 5A and 5B illustrate an exemplary simulated gastro-intestinal tract according to the present invention;

FIGS. 6A-C illustrate various aspects of one embodiment of the force-feedback system according to the present invention;

FIGS. 7A-7D illustrate a second embodiment of the force-feedback system according to the present invention;

FIGS. 8A-8E show another embodiment of the system according to the present invention; and

FIGS. 9A-9E show an illustrative embodiment of a tool unit according to the present invention.

BRIEF DESCRIPTION OF THE INVENTION

The present invention includes a method and a system to simulate the medical procedure of endoscopy, particularly of flexible gastro-endoscopy. The system is designed to simulate the actual medical procedure of endoscopy as closely as possible by providing both a simulated medical instrument, and tactile and visual feedback as the simulated procedure is

performed on the simulated patient. Although the discussion is directed toward the medical procedure of endoscopy, the present invention could also be employed to simulate other types of minimally invasive medical procedures.

The system of the present invention features both a physical model and a virtual model for the simulation of the medical procedure of endoscopy. The physical model includes a mannequin into which the simulated endoscope is inserted. A simulated organ is located within the mannequin. For example, if the simulated organ is the gastro-intestinal tract, the organ may optionally include a simulated rectum and a simulated colon for simulating the procedure of flexible gastro-endoscopy. Optionally and preferably, the simulated organ may optionally include a simulated mouth and upper gastro-intestinal tract. The simulated endoscope is inserted into the simulated gastro-intestinal tract. The simulated gastro-intestinal tract includes a tactile feedback system for providing realistic tactile feedback according to the movement of the simulated endoscope within the simulated organ.

The virtual model provides a "virtual reality" for the simulation of images from the endoscope. In an actual endoscopic medical procedure, a camera at the tip of the actual endoscope returns images from the gastro-intestinal tract of the human patient. These images are then viewed by the physician performing the endoscopic procedure, thereby providing visual feedback to the physician. The system of the present invention provides a "virtual reality" for the realistic simulation of this visual feedback. This virtual reality enables the real-time display of realistic images of the gastro-intestinal tract on a video monitor according to the manipulations of the simulated endoscope, preferably in such a manner that the tactile and visual feedback are linked as they would be in a human patient.

The virtual reality has two main components: a three-dimensional, mathematical model of the gastro-intestinal tract, or a portion thereof, and a database of enhanced digitized images derived from actual visual data obtained from actual endoscopic procedures. These two components are combined to provide realistic visual feedback by using the enhanced images as texture mapping to overlay the mathematical model of the simulated organ, thereby closely simulating images obtained from the actual procedure.

The virtual reality feedback of the gastro-intestinal tract is particularly advantageous for simulating images because it does not rely on video streams, which require massive computational power for real-time display of visual feedback. In addition, video streams provide only a predetermined flow of images and cannot provide visual data with six degrees

of freedom in real time. Furthermore, the virtual reality of the present invention does not rely merely on a mathematical model of the gastro-intestinal tract, which cannot capture the irregularities and subtle visual features of an actual gastro-intestinal tract from a human patient. Thus, the virtual reality feedback of the gastro-intestinal tract provides the best simulation of realistic images in real time for visual feedback.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The present invention is related to a method and a system to simulate the procedure of endoscopy, particularly of flexible gastro-endoscopy. The system includes a mannequin into which the simulated endoscope is inserted. Visual feedback is provided through a video monitor, which displays realistic images in real time, according to the manipulations of the simulated endoscope. Realistic tactile feedback is also provided, preferably in such a manner that the tactile and visual feedback are linked as they would be in a human patient. Preferably, the present invention also features a tutorial system for training students and testing their performance. Thus, the system and method of the present invention provide a realistic simulation of the medical procedure of endoscopy for training and testing students.

The principles and operation of a method and a system according to the present invention for medical simulation, and in particular for the simulation of the medical procedure of endoscopy, preferably including communicating tutorial results and measurement of student skills to the teacher or supervising medical personnel, may be better understood with reference to the drawings and the accompanying description, it being understood that these drawings are given for illustrative purposes only and are not meant to be limiting. Furthermore, although the description below is directed toward the simulation of the colon, it should be noted that this is only for the purposes of clarity and is not meant to be limiting in any way.

Referring now to the drawings, Figure 1 depicts an exemplary, illustrative system for medical simulation according to the present invention. A system **10** includes a mannequin **12** representing the subject on which the procedure is to be performed, a simulated endoscope **14** and a computer **16** with a video monitor **18**. A student **20** is shown interacting with system **10** by manipulating simulated endoscope **14** within mannequin **12**. As further illustrated in Figures 5A and 5B below, mannequin **12** includes a simulated organ into which simulated endoscope **14** is inserted. As student **20** manipulates simulated endoscope **14**, tactile and

visual feedback are determined according to the position of endoscope **14** within the simulated organ (not shown). The visual feedback are provided in the form of a display on video monitor **18**. The necessary data calculations are performed by computer **16**, so that realistic tactile and visual feedback are provided to student **20**.

Figure 2 is an exemplary illustration of a screen display shown on monitor **18**. A screen display **22** includes a feedback image **24**. Feedback image **24** represents the visual image as seen if the endoscope were inserted into a living human patient. Feedback image **24** is an accurate and realistic simulation of the visual data that would be received from that portion of the gastro-intestinal tract in the living human patient. Although feedback image **24** is shown as a static image, it is understood that this is for illustrative purposes only and the actual visual feedback data would be in the form of a substantially continuous flow of simulated images based upon actual video stream data obtained from an actual endoscopic procedure. Thus, the flow of images represented by feedback image **24** gives the student (not shown) realistic visual feedback.

In addition, screen display **22** preferably includes a number of GUI (graphic user interface) features related to the preferred tutorial functions of the present invention. For example, a tracking display **26** explicitly shows the location of the simulated endoscope within the simulated gastro-intestinal tract. Tracking display **26** includes a schematic gastro-intestinal tract **28**, into which a schematic endoscope **30** has been inserted. Preferably, tracking display **26** can be enabled or disabled, so that the student can only see tracking display **26** if the tracking function is enabled.

Additional, optional but preferred features of screen display **22** include the provision of a "help" button **32**, which upon activation could cause the display of such helpful information as a guide to the controls of the endoscope. Similarly, a preferred "hint" button **34** would give the student one or more suggestions on how to continue the performance of the medical procedure. A preferred "patient history" button **36** would cause screen display **22** to show information related to one of a selection of simulated "patient histories", which could be of help to the student in deciding upon a further action. Finally, a preferred "performance" button **38** would cause screen display **22** to display a review and rating of the performance of the student. All of these functions are part of the preferred embodiment of a tutorial system for training a student in the medical procedure of endoscopy, as described in further detail in Figure 4.

Figures 3A and 3B are schematic block diagrams of an exemplary visual processing and display system and method according to the present invention. Figure 3A is a flow chart of the method for visual processing and display according to the present invention, and is intended as a summary of the method employed by the system of Figure 3B. Further details concerning particular aspects of the method are described below with reference to Figure 3B.

The method and system of the present invention provide a solution to a number of problems in the art of medical simulation, in particular for the simulation of the procedure of gastro-endoscopy. This procedure involves the visual display of an interior portion of the gastrointestinal tract, such as the colon. The colon is a flexible body with a curved structure. The inner surface of the colon is generally deformable, as well as being specifically, locally deformable. All of these deformations in space must be calculated according to the mathematical model of the colon, and then rendered visually in real time in order to provide a realistic visual feedback response for the user.

Figure 3A shows a preferred embodiment of the method of the present invention for preparation of the model and rendering of visual feedback, including steps required for preparation of the computerized model of the colon, as well as steps required for display of the colon.

In step 1 of the method of the present invention, actual video data are recorded onto videotape during the performance of the actual medical procedure of endoscopy on a living human patient. In addition, such data could also include MRI (magnetic resonance imaging) and CAT (computer assisted tomography) scan data from procedures performed on living human patients.

In step 2, individual images are abstracted, for example with a framegrabber device, and then digitized. In step 3, the digitized images are preferably selected for clarity and lack of visual artifacts, and are then stored in a texture mapping database. More preferably, the digitized images are enhanced before being stored. Most preferably, the texture mapping also include animation. Such animation could simulate effects such as random vibration of the tissue of the colon or of the endoscope, as well as such events as liquid flowing downward due to the influence of gravity.

In step 4, a three-dimensional mathematical model of the human colon is constructed. The three-dimensional mathematical model of the colon which is particularly preferred for the present invention is a polygonal model such as a spline. This mathematical function

represents the colon as a series of curves, such that the points in the three-dimensional structure of the colon are mapped to the spline. For example, the colon could be modeled as a straight line which is deformed by altering the spline for the model until the model fits the data. Alternatively, the spline could be placed inside the colon and mapped to the colon. Preferably, multiple splines are used to model the junction of the stomach and small intestine, for example.

The mapping can be performed according to three-dimensional coordinates, along the x, y and z axes. Alternatively, the mapping can be performed according to coordinates of time, angle and radius within the colon. A mixture of these two different types of coordinates is also optionally employed, in which the coordinates are time, x and y for example. Both the spline itself and the mapping from the spline to the colon can optionally be altered in order to provide new and different visual representations of the colon, for example in order to provide a plurality of theoretical "test cases" for students to study. The alteration is optionally performed according to MRI (magnetic resonance imaging) data, for example. In addition, optionally and preferably data from MRI and/or CAT scan procedures are cleaned and reassembled according to the mathematical model, in order to more accurately determine the geometry of the simulated colon. Substantially all of these procedures could be performed automatically according to such data or alternatively, these procedures could also be performed partially or wholly manually. Thus, the preferred mathematical model of the present invention permits the data to be rapidly visually rendered onto the model of the colon.

According to a particularly preferred embodiment of the present invention, a "loop" of the endoscope cable itself is modeled. Such a loop occurs when the person performing the endoscopic procedure, whether "real" or simulated, inadvertently changes direction within the colon by turning the endoscope itself. Such a loop can be very dangerous to the patient, and therefore should be detected as part of a simulation, in order to warn the student as an indication that the procedure has been performed incorrectly thereby causing the loop to appear.

Preferably, the loop is constructed with a spline according to the present invention and is coordinated with force feedback. The length of cable which has been fed into colon must be determined, as must the length of the colon from the rectum (entry point of the endoscope) to the current position of the endoscope. The size of the loop is then calculated from the differential of these two lengths, and the loop is modeled according to the spline.

The method of visually rendering the colon according to the present invention includes a number of steps, described below, which are performed as software instructions operated by a data processor. The method preferably includes the step (shown as step 5 in Figure 3A) of dividing the colon into a plurality of portions. The division is made linearly, since the spatial movement of the simulated endoscope is limited. In other words, the simulated endoscope cannot "jump" from one portion of the colon to another, but must instead proceed in a linear fashion along the simulated colon. In addition, the simulated endoscope can only be moved at a finite speed through the simulated colon. Thus, the endoscope must pass through each segment of the three-dimensional model of the colon in sequence at a known, limited speed.

The consequences of such a division is that only one segment needs to be processed in any given moment, although a plurality of such segments could be processed substantially simultaneously if the computing resources were available. Furthermore, the division reduces the visual processing into a much more manageable task, since this model may optionally include thousands of polygons in the preferred embodiment, although each segment has far fewer polygons.

In addition, preferably only those portions which are in the line of sight of the camera, and hence either immediately visible or soon to become visible, are selected for visual rendering in order to decrease the computations required for the rendering. More preferably, the number of portions which are rendered is not predetermined, since under certain circumstances, the number of portions in the line of sight may vary. For example, when the camera is traveling around a bend in the colon, the line of sight of the camera is very short, such that relatively fewer portions, or else smaller such portions, must be rendered.

Next, in step 6, the visual attributes of the area of the colon being scanned by the camera are determined. Preferably, these visual attributes are determined according to a number of factors, including the location of the tip of the endoscope, which holds the camera, and the direction in which the camera itself is pointed. Other important factors include the shape of the colon being modeled and the history of movement of the camera through the colon. With regard to the latter factor, the previous movements of the endoscope through the colon, as determined by the actions of the student, have a significant impact on the area of the colon which is visualized by the camera at any given moment. For example, if the student has caused a "loop" to form by incorrectly operating the endoscope, as previously described, this "loop" can be simulated correctly only through the inclusion of the history of movements to

determine the visual feedback.

In step 7, preferably a local deformation to at least one of these portions is analyzed to determine if such a deformation affects the spline itself. The mapped coordinates are then rapidly transformed from time, angle and radius to x, y and z. Next, in step 8 preferably the local deformation of the tissue of the colon is determined through interpolation of the radius, in order to determine the degree of such deformation. Since the time, angle and radius may not give sufficient information to perform this calculation, optionally and preferably, the volume of the colon is additionally altered according to predefined mathematical models.

For deformations on a highly local scale, such as the point of contact between the tip of the endoscopic instrument and the colon at a low degree of force from the instrument, preferably the level of details in the area is increased by adding more polygons to the calculations performed with the model in order to be able to stretch all or substantially points in the immediate area without distortion. The stretching is preferably performed according to a predetermined function which preferably enables the spline model to be altered locally.

This preferred method for modeling "stretching" of the colon can also be used to model local areas of irregularity such as a polyp. Polyps can be mapped point by point onto the model of the colon, thereby adjusting the visual representation of the tissue to accommodate both the polyp itself and the structural alterations of the tissue at the base of the polyp.

Next, in step 9, the various types of data which were previously described are used to actually render the visual data onto the colon. Initially, the mapping of such data onto the model optionally and preferably involves some adjustments, performed manually by a software programmer. Alternatively, such mapping could be entirely automatically performed.

In step 10, texture mapping from the database is overlaid onto the chunk of the model. Preferably, such texture mapping includes both the digitized images and additional animation. In step 11, the resultant images are displayed. As noted previously, the images are displayed in a continuous flow according to the location of the simulated endoscope within the simulated gastrointestinal tract. Also as noted previously, such mapping of coordinates is preferably performed according to the mathematical model of the colon, which is more preferably a spline.

Figure 3B shows the visual processing and display system according to the present

invention in more detail. A visual processing and display system **40** includes screen display **22** for displaying the processed visual data. The visual data are constructed as follows. First, data are recorded from actual gastro-endoscopic procedures onto videotape, as shown in a recording block **42**. The data are preferably stored on Super-VHF videotape in order to obtain the highest quality representation of the visual images displayed on the screen during the actual endoscopic procedure, as shown in block **44**. Next, at least a portion of the frames of the videotape, and preferably substantially all the frames, are abstracted individually by a frame-grabber **46** to form digitized images. Individual digitized images can then be selected for clarity and lack of artifacts such as reflections from the endoscopic apparatus itself. The images in the selected frames are then preferably enhanced and added to a texture mapping database **48**.

Preferably, two types of texture mapping are stored in the database. The first type of texture mapping is intended to enhance the realistic visual aspects of the images, for example by removing visual artifacts. The second type of texture mapping is intended to simulate the behavior of a live organ and a real endoscope, as represented by block **50**. During actual endoscopic procedures on a living human patient, the tissue of the colon moves somewhat, and the endoscope itself vibrates and wobbles. This movement is simulated visually by the addition of random animation of the images, and also by the addition of such effects as liquid flowing downward due to the influence of gravity. Such animation enhances the realistic nature of the visual representation of the colon.

In order for the enhanced images to be correctly displayed, the images must correspond to the manipulation and location of the simulated endoscope within the simulated colon. In particular, the texture mapping of the images should correspond to the location of the endoscope within the colon. Such correspondence between the location of the endoscope within the colon and the texture mapping is provided by a texture mapping engine **52**. The texture mapping data is then readily accessed by the display portion of visual system **40**, as shown by block **54**.

However, as noted for previous prior art devices, simply reproducing the selected enhanced frames in a massive video stream would quickly overwhelm the computational resources and cause the visual display to become unsynchronized from the physical location of the simulated endoscope. Furthermore, such a video stream would not enable the correct display of images according to the movement of the endoscope, which preferably has six

degrees of freedom. Thus, mere reproduction is not sufficient to ensure realistic images, even when mapped onto a three-dimensional surface.

Preferably, visual processing and display system **40** includes a three-dimensional mathematical model of at least a portion of the gastro-intestinal tract **56**, more preferably constructed as described in Figure 3A. For the purposes of discussion, model **56** is herein described as a three-dimensional model of the colon, it being understood that this is not meant to be limiting in any way. Model **56** preferably features a plurality of segments **58**, more preferably many such segments **58**.

As the simulated endoscope moves along the simulated colon, the location of the endoscope is given to a locator **60**, described in further detail below. Locator **60** then instructs an object loader **62** to load the relevant segment **58** for access by visual system **40**, as shown in block **54** and previously described. In the preferred embodiment shown, preferably three segments **58** are ready for access by object loader **62** at any given moment. The specific segment **58** in which the endoscope is currently located is preferably held in DRAM or RAM, in combination with the texture mapping described previously. The next segment **58** and the preceding segment **58** preferably are also stored in an easily accessible location, although not necessarily in RAM or DRAM.

Preferably, the display of each image from specific segment **58** into which the simulated endoscope has entered is optimized by a segment optimizer **64**. Segment optimizer **64** receives information from locator **60**, as well as the series of images obtained from overlaying the texture mapping onto the relevant segment **58**, and then feeds each specific image to a display manager **66** for display on screen display **22**.

In addition, display manager **66** is assisted by a real-time viewer **68**, preferably implemented in Direct 3D™ (Microsoft Inc., Seattle, Washington). Real-time viewer **68** provides the necessary software support to communicate with a graphics card **70** for actual display of the images on screen display **22**. Although graphics card **70** can be of any suitable manufacture, preferably graphics card **70** has at least 8, and more preferably at least 16, Mb of VRAM for optimal performance. An example of a suitable graphics card **70** is the 3Dfx Voodoo Rush™ card. Preferably, the performance of real-time viewer **68** is enhanced by a math optimizer **72**, preferably implemented in Visual C++.

The interaction between segment optimizer **64** and display manager **66** on the one hand, and locator **60** on the other, is provided through a software interface **74**. Software

interface **74** enables locator **60** to communicate with the other components of visual system **40**, in order to provide information regarding the location of the endoscope within the colon.

In preferred embodiments of the present invention, locator **60** includes a sensor **76**, which can be obtained from Ascension Technology Corp., for example. Sensor **76** senses positional information from within a simulated organ **77**, which is described herein as a colon for the purposes of discussion and is not meant to be limiting. Sensor **76** is controlled by a control unit **82**. The positional information is then relayed to a CPU controller **78**, which is connected to a servo-motor **80** (Haydon Switch and Instrument Co.). As the simulated endoscope moves through the colon, the endoscope contacts different portions of the colon (not shown; see Figures 5 and 6 below). Tactile feedback is provided by each servo-motor **80** in turn, which manipulates the material of the colon.

Visual system **40** also includes a user interface **84**, preferably implemented in Visual C++. User interface **84** includes the GUI features described previously for Figure 2. In addition, user interface **84** enables visual system **40** to interact with the preferred feature of a network interface **86**, for example, so that other students can view screen display **22** over a network. User interface **84** also permits the tutorial functions of at least one, and preferably a plurality of, tutorial modules **88** to be activated. Tutorial module **88** could include a particular scenario, such as a subject with colon cancer, so that different types of diagnostic and medical challenges could be presented to the student. The student would then need to respond correctly to the presented scenario.

An example of the tutorial system is illustrated in more detail in the block diagram of Figure 4. A tutorial system **90** starts as shown in block **92**. Next, the user must select whether actual interaction with the simulated endoscope is desired, or if the user prefers to receive tutoring in the theory of endoscopy, as shown in a block **94**. The next display asks if the user is new, as shown in a block **96**. If the answer is "yes", the user is requested to enter certain information, as shown by block **98**. If the answer is "no", the user is requested to enter identification information, such as user name or identification number, as shown in block **100**.

Next, the user must select the type of tutoring. For example, the user could select tutoring by subject **102**, tutoring by procedures **104** or tutoring by case studies **106**. Tutoring by subject **102** includes, but is not limited to, such subjects as basic manipulation of the endoscope, biopsy and polypectomy. Tutoring by subject **102** includes on-screen support, as shown in block **108**.

Tutoring by case studies **106** can be selected both according to case number and according to the level of the desired cases, such as beginner, intermediate and expert. Preferably, individual case studies could be created by a teacher or professor, by combining features of various stored cases. For example, a professor could create a case history appropriate for a 20 year old male with colitis, so that the student would then be able to practice endoscopy on such a patient. Thus, tutoring system **90** preferably has the flexibility to enable many different types of "patients" to be studied.

If desired, on-screen support can be provided for both tutoring by case studies **106** and tutoring by procedures **104**, as shown in block **110**. If on-screen support is not desired, the user can indicate whether the tutoring session is actually an official test, as shown in block **112**. Thus, tutoring system **90** includes both the ability to teach and the ability to test the student.

According to a preferred embodiment of the present invention, the tutorial system also includes a simplified version of the simulated endoscopic process for teaching the proper manipulation of the endoscope according to visual feedback, as well as for enabling the student to understand the correspondence between the visual feedback and tactile feedback. This simplified version would emphasize the performance and mastery of one or more specific tasks, such as the manipulation of the endoscope through the colon.

Indeed, this preferred embodiment could be generalized to a method for teaching a particular skill required for performance of an actual medical procedure to a student. This method would include the step of abstracting a portion of the visual feedback of the actual medical procedure, which would preferably include fewer visual details than the entirety of the visual feedback obtained during the performance of the medical procedure. This portion of the visual feedback would preferably enable the student to learn the motion of the instrument as the required skill.

For example, the simplified version may optionally not feature many, or even most, of the visual details of the colon as visual feedback. Instead, the colon would preferably be presented as a smooth, relatively featureless tube having the geometry and dimensions of the colon in order to correlate the motion of the simulated endoscope through the interior space of the colon. More preferably, the simplified version would be embodied as a game, in which students would be awarded points for correct manipulation of the endoscope, and would be penalized for incorrect manipulations. Thus, the student would have the opportunity to learn

the manipulations required for successful endoscopy without the distraction of visual details, in a low pressure and even "fun" environment.

Figures 5A and 5B illustrate the mechanical aspects of an exemplary simulated gastro-intestinal tract according to the present invention. A cut-away view of a mannequin **114** is shown in Figure 5A. Preferably, mannequin **114** is about one meter wide, which is within the dimensions of an actual human subject. A simulated gastro-intestinal tract **116** is shown within mannequin **114**. For the purposes of clarity, simulated gastro-intestinal tract **116** includes only the colon, it being understood that this is not meant to be limiting in any way. Simulated gastro-intestinal tract **116** is connected to a transmitter **118** and a signal processing device **120**, also placed within mannequin **114**. As shown, a simulated endoscope **122** can be inserted into mannequin **114** through an opening **124**. In this case, since the simulation is for endoscopy of the colon of the subject, opening **124** simulates the rectum of the subject.

Simulated endoscope **122** can be maneuvered left, right, up and down. Preferably, simulated endoscope **122** is about 1800 cm long, similar to the length of a real endoscope. Also preferably, the diameter of the tip of simulated endoscope **122** is about 13.4 mm, while the remainder of endoscope **122** has a diameter of about 10.2 mm, again similar to the dimensions of a real endoscope.

Once simulated endoscope **122** is inserted into simulated gastro-intestinal tract **116**, sensor **76** on the tip of simulated endoscope **122** is able to detect the location of simulated endoscope **122**. Sensor **76** preferably has three degrees of freedom, more preferably six degrees of freedom for effective simulation of manipulation of endoscope **122**. If sensor **76** has six degrees of freedom, the detected directions of orientation include the Cartesian coordinates X, Y, Z, as well as roll, elevation and azimuth. In addition, sensor **76** preferably includes a sensor transmitter **126**, so that the precise angle and location of sensor **76** can be determined relative to gastro-intestinal tract **116**. Sensor transmitter **126** transmits data to signal processing device **120**, which then analyzes and processes the signal. The processed signal is then given to transmitter **118** for transmission to an electronics unit **128** and a DC drive unit **130**. The signal is converted by DC drive unit **130** and passed to electronics unit **128**. Electronics unit **128** then sends the position and orientation of sensor **76** to software interface **74**, so that the remainder of the display system is able to use the information to display the correct images on display screen **22** for visual feedback.

The present invention provides both visual feedback and tactile feedback. Tactile

feedback can be provided through the exertion of forces on simulated endoscope **122** by simulated gastro-intestinal tract **116**, as shown in Figures 6A-6C. Alternatively, tactile feedback could be provided by the mechanical action of simulated endoscope **122**, as shown in Figures 7A-7D. For the first embodiment, preferably simulated gastro-intestinal tract **116** is constructed from semi-flexible material, which gives the feel of a smooth and wet material. Of course, the actual sensations of sliding along a semi-flexible, smooth, wet material can also be provided through the mechanism of endoscope **122** itself, as in the second embodiment.

An additional embodiment of gastro-intestinal tract **116**, in which tract **116** is placed within a box **132** rather than within mannequin **114**, is shown in Figure 5B. The advantage of box **132** is that box **132** could serve to contain any radiowaves, so that the mechanism of gastro-intestinal tract **116** could be controlled by transmission of radiowaves, for example. Since certain medical equipment is highly sensitive to these radiowaves, they would need to remain within mannequin **114**. Box **132** would therefore act to insulate gastro-intestinal tract **116** from the external environment outside the mannequin. Details of gastro-intestinal tract **116** are more readily seen in Figure 6A, it being understood that Figures 5A, 5B and 6A illustrate the same gastro-intestinal tract **116**.

Figure 6A shows gastro-intestinal tract **116** according to the first embodiment, in which tactile feedback is provided by forces acting on simulated endoscope **122** by a mechanism contained within gastro-intestinal tract **116** itself. Simulated gastro-intestinal tract **116** is made from a semi-flexible material. A plurality of motion boxes **134** are disposed at intervals along the outer surface of gastro-intestinal tract **116**. For the purposes of illustration, seven motion boxes **134** are shown. Each motion box **134**, shown in greater detail in Figure 6B, has at least one, and preferably a plurality of, servo-motors **80**, preferably linear motors.

Each servo-motor **80** is connected to a piston **136**. The detail of piston **136** is shown enlarged in Figure 6B. Each piston **136** is connected to a foot **138**, which contacts a portion of the material of the external surface of gastro-intestinal tract **116**. Preferably, foot **138** is actually attached to the portion of the material of the external surface, for easier manipulation of the material.

Preferably, there are two different types of pistons **136**. The first type, of which two are shown for illustrative purposes, is a vertical force piston **140** for causing vertical movement of a portion of the external surface of gastro-intestinal tract **116**. The second type, of which one is shown for illustrative purposes, is a horizontal force piston **142** for causing

horizontal movement of a portion of the external surface of gastro-intestinal tract **116**. In the preferred embodiment shown, servo-motor **80** is an oscillating motor placed directly against the material of gastro-intestinal tract **116**, so that horizontal force piston **142** includes the motor alone, without a structure similar to vertical force piston **140**. Since each piston **136** has an associated servo-motor **80**, the necessary vertical and horizontal movement of the external surface of gastro-intestinal tract **116** can be precisely determined by the activity of servo-motor **80**.

Each piston **136**, or preferably attached foot **138**, contacts the material of gastro-intestinal tract **116** in order to manipulate this material to exert a force against the endoscope (not shown). For example, as shown in Figure 6B, a first vertical force piston **144** could be moved closer to servo-motor **80**, while a second vertical force piston **146** is moved away from servo-motor **80**. These movements alter the position of the material of gastro-intestinal tract **116**, causing forces to be exerted against the simulated endoscope similar or identical to those felt during an actual endoscopic procedure. In addition, horizontal force piston **142**, which is preferably an oscillating servo-motor alone as shown, moves horizontally to provide more delicate fine-tuning of the tactile feedback sensations. Since servo-motors **80** are disposed over the three-dimensional surface of gastro-intestinal tract **116**, the force on the endoscope can be exerted in three dimensions.

The activity of servo-motor **80** is in turn controlled by digital controller **82**. Digital controller **82** can be a card inserted within the PC computer which is performing the requisite calculations required for the simulation of the medical process. Software operated by the PC computer uses positional and orientation information from sensor **76** on simulated endoscope **122** to determine the position of simulated endoscope **122**. Next, the software sends instructions to digital controller **82** according to the desired tactile sensations which should be felt by the operator of simulated endoscope **122** at that particular position within simulated gastro-intestinal tract **116**. Digital controller **82** then causes at least one servo-motor **80** to move the associated piston **136** as necessary to provide the tactile feedback sensations.

Digital controller **82** can be connected to servo-motors **80** through some type of radiation, such as infra-red light. However, the limitations on radiation of certain wavelengths, such as radiowaves, within the hospital or medical environment, make a connection by an actual wire running from digital controller **82** to each servo-motor **80** more preferable. In the exemplary embodiment shown in Figure 6B, each servo-motor **80** is

connected to a motion box controller **144** by a wire. Motion box controller **144** is then preferably connected to digital controller **82** by a single wire (not shown). This configuration limits the number of individual connections made to digital controller **82** for greater efficiency.

Figure 6C shows an enlarged cut-away view of servo-motor **80**, which as noted previously is preferably a linear motor. Preferably, servo-motor **80** is about 100 mm wide and 45 mm tall.

Figures 7A-7D show a second embodiment of the mechanism for providing tactile feedback. In this embodiment, the mechanism is contained within the simulated endoscope itself, rather than the simulated gastro-intestinal tract. Similar to the previous embodiment, the simulated gastro-intestinal tract could be contained within a substantially life-size mannequin with an opening for simulating the rectum. Furthermore, from the viewpoint of the student or other individual operating the simulated endoscope, both embodiments should give a suitable simulation of the medical procedure. However, as detailed below, the actual mechanism of providing the tactile portion of the simulation differs.

Figure 7A shows the second embodiment of a simulated endoscope **146**. The movements and actions of simulated endoscope **146** are controlled through a set of controls **148**. The tip of simulated endoscope **146** is contained within a guiding sleeve **150**. Guiding sleeve **150**, shown in greater detail in Figure 7B, preferably remains within the simulated gastro-intestinal tract (not shown; see Figure 7C) in order to maintain a realistic visual appearance of simulated endoscope **146** before insertion into the mannequin (not shown). Preferably, the tip of endoscope **146** has a metal bracket **152** attached, which could be labeled with the word "sample" or with another label in order to clarify that endoscope **146** is only a simulation and not an actual medical instrument. The inside of guiding sleeve **150** is preferably magnetized, for example with an electric current. Thus, when the tip of endoscope **146** is inserted in the mannequin, metal bracket **152** is attracted to guiding sleeve **150** so that guiding sleeve **150** remains attached to the tip of endoscope **146**.

Guiding sleeve **150** has at least one, and preferably a plurality of, ball bearings **154** attached to the exterior surface of guiding sleeve **150**. In addition, guiding sleeve **150** has at least one, and preferably a plurality of, attached plungers **156**. As shown in the detailed view in Figure 7B, one end of guiding sleeve **150** preferably features a section of flexible material **158**. As shown, the tip of endoscope **146** is preferably inserted through guiding sleeve **150**.

The tip of endoscope **146** features sensor **76**, as for the previous embodiment of the simulated endoscope.

Figure 7C shows simulated endoscope **146** after insertion within the second embodiment of a simulated gastro-intestinal tract **160**. Simulated gastro-intestinal tract **160** is preferably constructed from a rigid material. In addition, simulated gastro-intestinal tract **160** preferably has the general anatomical shape and features of an actual gastro-intestinal tract for two reasons. First, the general anatomical shape can be more easily contained within the mannequin because of its bends and turns. Second, the general anatomical shape can provide gross tactile feedback. For example, as any endoscope is inserted more deeply into the colon, the shape of the colon causes the tactile sensations to be altered as the endoscope moves around a bend in the colon. Thus, the general anatomical shape is more useful for an effective simulation.

As endoscope **146** moves within simulated gastro-intestinal tract **160**, guiding sleeve **150** enables the operator to receive tactile feedback as follows. Ball bearings **154** roll along the interior surface of gastro-intestinal tract **160**. Each ball bearing **154** has five degrees of freedom for movement. Each plunger **156** is connected to a linear motor **162**, as shown in cross-section in Figure 7D. Linear motor **162** is controlled in a similar fashion as the servo-motor of the previous embodiment. Upon receipt of signals from the computer, linear motor **162** causes plunger **156** to move vertically, thereby causing the operator of simulated endoscope **146** to receive tactile feedback sensations. Thus, guiding sleeve **150** causes tactile feedback to be transmitted back through endoscope **146**.

In addition, as noted above guiding sleeve **150** preferably has section of flexible material **158**. Section of flexible material **158** causes the tip of endoscope **146** to encounter some resistance under certain circumstances, such as when the tip is bent back on itself. Thus, section of flexible material **158** restrains movement of the tip from certain angles.

The particular advantages of this second embodiment is that the majority of tactile sensations are determined by the endoscope itself, so that they can be more easily controlled from the PC computer. Furthermore, such anatomical features as a fistula can be added according to instructions from the computer, without the necessity of changing the physical model of the simulated gastro-intestinal tract. Additionally, under certain circumstances the tissue of the actual colon will force the endoscope backwards, a situation which can be more easily replicated in the second embodiment. Thus, the second embodiment of the simulated

gastro-intestinal tract and endoscope is more flexible in terms of replicating a greater variety of anatomical features and conditions.

Figures 8A-8E show yet another and particularly preferred embodiment of the simulated endoscope and colon according to the present invention. Figure 8A shows a preferred system for medical simulation according to the present invention. A system **164** includes a mannequin **166** representing the subject on which the procedure is to be performed, a simulated endoscope (not shown, see Figure 8D) and a computer **168** with a video monitor **170**. Mannequin **166** preferably includes a palpable area **172** for determining the location of the simulated endoscope by feeling the abdominal area of mannequin **166**. Palpable area **172** preferably features a light (not shown), such that when the student has determined the location of the simulated endoscope, the light is lit to show the actual location of the simulated endoscope.

Mannequin **166** also includes a simulated organ **174** into which the simulated endoscope is inserted. Preferably, simulated organ **174** is a colon, which more preferably is constructed as a straight tube, with the force feedback required for the curves in the colon provided through a force feedback mechanism **176**. More preferably, the visual feedback for the simulated medical procedure does not depend upon the geometrical shape of simulated organ **174** itself, such that the visual feedback and the tactile feedback are both substantially completely independent of the construction of simulated organ **174**.

Force feedback mechanism **176** preferably includes an air-driven force feedback device **178** (shown in more detail in Figures 8B, 8D and 8E). More preferably, two such air-driven force feedback devices **178** are provided, one near a mouth **180** of mannequin **166**, and the other near a rectum **182** of mannequin **166**. An air tube **184** connects each air-driven force feedback device **178** to an air-pump **186**. Preferably, air-pump **186** also includes an air-pump control unit **188** which is connected to computer **168** for controlling the amount of air pumped into air-driven force feedback device **178**.

Computer **168** also preferably includes a modem **190** for communication with other computers. For example, modem **190** could enable computer **168** to connect to the Internet or intranet for performing telemedicine, or to connect to the intranet/computer network of the manufacturer for repair or trouble-shooting.

Figures 8B and 8C show components of air-driven force feedback device **178** in more detail. As shown in Figure 8B, a portion of a simulated endoscope **192** interacts with air-

driven force feedback device **178** to provide force feedback to the student. Force feedback device **178** features a plurality of inflatable rings **194** (shown in more detail in the fully inflated position in Figure 8C). Each inflatable ring **194** preferably has a different radius. More preferably, there are four such rings **194**, at least one of which has a larger radius than endoscope **192** and at least one of which has a smaller radius than endoscope **192**. The amount of air fed into rings **194** determines the degree of inflation of each ring **194**, preferably separately, thereby determining the amount of force exerted onto endoscope **192**.

Preferably, each ring **194** requires one second or more preferably less than one second to reach the fully inflated position. The air flow rate is preferably up to 100 liters per minute and the pressure is up to 3 atmospheres. Rings **194** are preferably used both for passive force feedback, such as from the contraction of the rectum, and for active force feedback, for example when air is pumped into simulated organ **174** according to a functional feature of simulated endoscope **192** (see Figure 8E).

Figure 8D shows force feedback mechanism **176** in more detail. Preferably, rings **194** are connected to air pump **186** through tube **184**, which more preferably is split into two tubes **196**, a first tube **196** for pumping air into rings **194**, and a second tube **196** for pumping air from rings **194**. The amount of air pumped by air pump **186** is controlled by air pump controller **188**. The actions of air pump controller **188** are preferably controlled by computer **168** through an I/O (analog-to-digital) card **198**.

Figure 8E shows simulated endoscope **192** in more detail. Simulated endoscope **192** features a handle **200** with various controls, including a first control **202** for pumping air into simulated organ **174**, and a second control **204** for suctioning air out of simulated organ **174**. Simulated endoscope **192** preferably features a surgical tool control device **206** into which various surgical tools are optionally and preferably inserted (see Figures 9A-9E). Simulated endoscope **192** also preferably features a receiver **208**, for example a "minibird" sensor (Ascension Ltd., Burlington, Vermont, USA). Receiver **208** is located at the tip of simulated endoscope **192**. Receiver **208** is designed to receive transmissions from a transmitter **210** located in mannequin **166** (see Figure 8A), thereby determining a position of the tip of simulated endoscope **192** within simulated organ **174**. Transmitter **210** is preferably a "minibird" transmitter (Ascension Ltd.). Receiver **208** then transmits these signals to computer **168**, which uses these signals for determining the amount of force feedback and the visual feedback to be displayed to the student on monitor **178**.

As previously described. Figures 9A-9E show a preferred implementation of surgical tool control device **206** into which various surgical tools are optionally and preferably inserted. Surgical tool control device **206** preferably features a forceps **212** inserted into a tool sleeve **214**, thereby simulating actual forceps for an endoscope. Actual forceps are used for performing a polypectomy, and feature a loop which emerges from the tip of the forceps upon manipulation of the device. This loop is placed around the polyp and drawn tight. Electricity is then sent through the loop in order to cut the polyp and to cauterize the area.

Similar to actual forceps. forceps **212** is inserted as the student holds a forceps handle **216**, preferably including a button or other control for simulating the effects of starting the flow of "electricity" through the "loop". Tool sleeve **214** features a tool control unit **218** for detecting the motions of forceps **212**, and translating these motions into force feedback and visual feedback. Visual feedback includes the visual display of the forceps "loop" when appropriate, for example, as well as the display of the polyp before and after the "polypectomy". In addition, the location of the loop must be tracked, preferably including up and down movements within the endoscope, and "roll" movement of the loop. Tool control unit **218** is connected to an I/O card within the computer (not shown) for performing the necessary calculations for the various types of feedback.

Figures 9B and 9C show two views of forceps **212** interacting with tool control unit **218** within tool sleeve **214**. Tool control unit **218** features a guide wheel **220** and a light wheel **222** for detecting the motions of forceps **212** (Figure 9B). Light wheel **222** features a plurality of notches through which light may pass. Tool control unit **218** also features a first light **224** and a first light sensor **226**, as well as a second light **228** and a second light sensor **230** (Figure 9C). As light wheel **222** turns with the motion of forceps **212**, light passing from first light **224** and second light **228** is alternately blocked and unblocked, such that light is alternately detectable and non-detectable by first light sensor **226** and second light sensor **230**.

Figure 9C shows a second embodiment of the tool control unit. In this embodiment, a tool control unit **232** features two guide wheels **234**. Guide wheels **234** help to guide the movement of forceps **212** within tool sleeve **214**. A light wheel **236** also features notches through which light is alternately blocked and unblocked as forceps **212** is rotated within tool sleeve **214**. A light source (not shown) produces light which is detected. if it passes through light wheel **236**, by a photoelectric eye **238**. Photoelectric eye **238** then sends signals to a PCB (printed circuit board) **240** which is connected to the computer (not shown), such that these

signals can be translated by the computer into the required visual feedback and force feedback.

A foot pedal 242 is shown in Figure 9E for performing a simulated polypectomy. Foot pedal 242 features an oil piston 244 and a microswitch 246. Microswitch 246 is connected to an I/O card on the computer (not shown), again for translating the movement of foot pedal 242 into the required visual feedback and force feedback.

In order to accurately replicate the tactile sensations of an actual endoscope during a medical procedure, these sensations must be accurately obtained during an endoscopic procedure in an actual living patient. For example, such tactile sensations could be collected from a physician performing the endoscopic procedure while wearing virtual reality gloves, such as the DataGloves™ Tracking VR System (Greenleaf Medical Systems). These gloves are known for being able to register data regarding tactile sensations and feedback as experienced by the physician during the actual endoscopic procedure. Such actual data are important because the tactile sensations change during the course of the procedure. For example, correlation between the movement of the endoscope and the visual display is gradually decreased as the endoscope is inserted deeper into the gastro-intestinal tract. Thus, the collection of actual data is an important step in the provision of an accurate, realistic endoscopic simulator.

Finally, according to another preferred embodiment of the present invention there is provided a simulated biopsy device (not shown). This biopsy device would simulate the actual biopsy device used to retrieve tissue samples from the gastro-intestinal tract during endoscopy. The actual biopsy device is contained within the endoscope. When the operator of the endoscope wishes to take a sample, the biopsy device emerges from the tip of the endoscope, at which point it is visible on the display screen. The jaws of the biopsy device are then opened and pushed onto the tissue. The jaws are then closed, and the biopsy device retracted. The removal of the tissue causes pools of blood to appear as the remaining tissue bleeds.

Similarly, the simulated biopsy device will only appear on the display screen of the present invention when the operator of the simulated endoscope causes the simulated biopsy device to emerge. The jaws of the biopsy device are preferably rendered as animation, more preferably in relatively high resolution because the jaws are small, so that a high resolution would not prove unduly taxing for the PC computer. The bleeding of the tissue and the

resultant pools of blood will also be animated.

It will be appreciated that the above descriptions are intended only to serve as examples, and that many other embodiments are possible within the spirit and the scope of the present invention.

WHAT IS CLAIMED:

1. A system for performing a simulated medical procedure, comprising:

(a) a simulated organ;

(b) a simulated instrument for performing the simulated medical procedure on said simulated organ;

(c) a locator for determining a location of said simulated instrument within said simulated organ; and

(d) a visual display for displaying images according to said location of said simulated instrument within said simulated organ for providing visual feedback, such that said images simulate actual visual data received during an actual medical procedure as performed on an actual subject, said visual display including:

  (i) a mathematical model for modeling said simulated organ according to a corresponding actual organ, said model being divided into a plurality of segments;

  (ii) a loader for selecting at least one of said plurality of segments for display, said at least one of said plurality of segments being selected according to said location of said simulated instrument within said simulated organ;

  (iii) a controller for selecting a simulated image from said segment according to said location of said simulated instrument; and

  (iv) a displayer for displaying said simulated image.

2. The system of claim 1, wherein said visual displayer further comprises:

(v) a texture mapping database for storing texture mapping data; and

(vi) a texture mapping engine for overlaying said simulated image with said texture mapping data substantially before said simulated image is displayed by said displayer.

3. The system of claim 2, wherein said texture mapping is animation of random movement of said simulated instrument and random movement of said simulated organ.

4. The system of claim 1, wherein said texture mapping includes images obtained from performing said actual medical procedure on said actual subject.

5. The system of claim 4, wherein said images are obtained by first recording said visual data during said performance and then selecting said images from said recorded visual data.

6. The system of claim 1, wherein said mathematical model features a plurality of polygons constructed according to a spline, said spline determining a geometry of said mathematical model in three dimensions.

7. The system of claim 6, wherein a deformation in said mathematical model corresponding to a deformation in said simulated organ is determined by altering said spline.

8. The system of claim 7, wherein said deformation in said simulated organ is a local deformation, said local deformation of said simulated organ being determined according to said mathematical model by adding polygons to a portion of said mathematical model, such that said portion of said mathematical model is deformed to produce said local deformation.

9. The system of claim 6, wherein said mathematical model is constructed from said spline by modeling said simulated organ as a straight line and altering said spline until said mathematical model fits said corresponding actual organ.

10. The system of claim 9, wherein said controller selects said simulated image according to at least one previous movement of said simulated instrument within said simulated organ.

11. The system of claim 1, wherein said displayer further displays a graphical user interface.

12. The system of claim 11, wherein said graphical user interface displays tutorial

information for aid in performing the medical procedure.

13. The system of claim 1, wherein said simulated organ is a gastro-intestinal tract.

14. The system of claim 13, wherein said gastro-intestinal tract is constructed from a semi-flexible, smooth material.

15. The system of claim 13, wherein said simulated instrument is an endoscope, said endoscope featuring a sensor for determining a location of said sensor in said gastro-intestinal tract, the system further comprising:

(e) a computer for determining said visual feedback according to said location of said sensor.

16. The system of claim 15, further comprising a tactile feedback mechanism for providing simulated tactile feedback according to said location of said tip of said endoscope.

17. The system of claim 16, wherein said tactile feedback mechanism is contained in said gastro-intestinal tract, and said gastro-intestinal tract further comprises:

(i) a plurality of servo-motors;
(ii) a piston operated by each of said plurality of servo-motors, said piston contacting said semi-flexible material; and
(iii) a controller for controlling said plurality of servo-motors, such that a position of said piston is determined by said controller, and such that said position of said piston provides said tactile feedback.

18. The system of claim 16, wherein said tactile feedback mechanism is located in said endoscope, and said endoscope further comprises:

(i) a guiding sleeve connected to said tip of said endoscope;
(ii) at least one ball bearing attached to said guiding sleeve for rolling along an inner surface of said gastro-intestinal tract;
(iii) at least one linear motor attached to said guiding sleeve;
(iv) a piston operated by said linear motor, said piston contacting said inner surface

of said gastro-intestinal tract; and

(v) a controller for controlling said linear motor, such that a position of said piston is determined by said controller, and such that said position of said piston provides said tactile feedback.

19. The system of claim 16, wherein said tactile feedback mechanism features:

(i) a plurality of rings surrounding said endoscope, each ring having a different radius, at least a first ring featuring a radius greater than a radius of said endoscope and at least a second ring featuring a radius less than said radius of said endoscope, said radius of each of said plurality of rings being controlled according to a degree of inflation with air of each of said plurality of rings, said radius of said rings determining movement of said endoscope;

(ii) an air pump for pumping air into said plurality of rings;

(iii) at least one tube for connecting said air pump to said plurality of rings; and

(iv) an air pump controller for determining said degree of inflation with air of said plurality of rings by controlling said air pump.

20. The system of claim 19, wherein said at least one tube is two tubes, a first tube for pumping air into said plurality of rings and a second tube for suctioning air from said plurality of rings, and said air pump pumps air into said plurality of rings and sucks air from said plurality of rings, such that said degree of inflation with air of said plurality of rings is determined by alternately pumping air into, and suctioning air from, said plurality of rings.

21. The system of claim 16, wherein said gastro-intestinal tract is a substantially straight tube, such that said tactile feedback and said visual feedback are substantially independent of a geometrical shape of said gastro-intestinal tract.

22. The system of claim 16, wherein said tactile feedback mechanism is operated according to tactile feedback obtained during said performance of the medical procedure on an actual subject, said tactile feedback being obtained through virtual reality gloves.

23. The system of claim 15, wherein said endoscope further features a handle for

holding said endoscope and a tool unit, said tool unit comprising:

(i) a simulated forceps;

(ii) a channel for receiving said simulated forceps, said channel being located in said handle;

(iii) a tool control unit for detecting a movement of said simulated forceps, said tool control unit being located in said channel and said tool control unit being in communication with said computer, such that said computer determines said visual feedback and said tactile feedback according to said movement of said simulated forceps.

24. The system of claim 23, wherein said tool control unit detects a location of said simulated forceps within said gastro-intestinal tract for providing visual feedback.

25. The system of claim 24, wherein said tool control unit additionally detects a roll of said simulated forceps for providing visual feedback.

26. The system of claim 25, wherein said visual feedback includes a display of a simulated loop of said simulated forceps for performing a polypectomy.

27. The system of claim 23, wherein said tool control unit further comprises:

(1) a light source for producing light, said light source being located in said channel;

(2) a light wheel for alternately blocking and unblocking said light according to said movement of said simulated forceps; and

(3) a light detector for detecting said light, such that said computer determines a movement of said simulated forceps according to said light detector.

28. A method for performing a simulated endoscopic procedure, comprising the steps of:

(a) providing a system for performing the simulated endoscopic procedure, comprising:

(i) a simulated gastro-intestinal tract;

(ii) a simulated endoscope for performing the simulated endoscopic procedure on said simulated gastro-intestinal tract;

(iii) a locator for determining a location of said simulated endoscope within said simulated gastro-intestinal tract; and

(iv) a visual display for displaying images according to said simulated endoscope within said simulated gastro-intestinal tract, such that said images simulate visual data received during an actual medical procedure as performed on an actual subject, said visual display including:

(1) a three-dimensional mathematical model of said simulated gastro-intestinal tract, said model being divided into a plurality of segments;

(2) a loader for selecting at least one of said plurality of segments for display, said at least one of said plurality of segments being selected according to said location of said simulated endoscope within said simulated gastro-intestinal tract;

(3) a controller for selecting a simulated image from said segment according to said location of said simulated instrument; and

(4) a displayer for displaying said simulated image according to said controller, such that said simulated image is a displayed image;

(b) inserting said simulated endoscope into said simulated gastro-intestinal tract;

(c) receiving visual feedback according to said displayed image; and

(d) receiving tactile feedback according to said location of said endoscope within said gastro-intestinal tract.

29. The method of claim 28, wherein said displayed image is determined according to at least one previous movement of said simulated endoscope within said simulated gastro-intestinal tract.

30. A method for displaying simulated visual data of a medical procedure performed on an actual human organ with an actual medical instrument, the method comprising the steps of:

(a) recording actual data from a performance of an actual medical procedure on a

living human patient;

(b) abstracting a plurality of individual images from said actual data;

(c) digitizing said plurality of individual images to form a plurality of digitized images;

(d) selecting at least one of said plurality of digitized images to form a selected digitized image;

(e) storing said selected digitized image as texture mapping data in a texture mapping database;

(f) providing a mathematical model of the actual human organ, said model being divided into a plurality of segments;

(g) selecting one of said plurality of segments from said model for display;

(h) overlaying said texture mapping data from said texture mapping database onto said segment of said model to form at least one resultant image; and

(i) displaying said resultant image.

31. The method of claim 30, wherein said actual data from said performance of said actual medical procedure is selected from the group consisting of video data, MRI (magnetic resonance imaging) data and CAT (computer assisted tomography) scan data.

32. The method of claim 31, wherein step (f) further comprises the steps of:

(i) modeling the actual human organ as a plurality of polygons according to a spline;

(ii) mapping said spline to the actual human organ according to three-dimensional coordinates;

(iii) altering said spline such that said spline fits said actual data.

33. The method of claim 22, wherein said texture mapping data further include animation.

34. The method of claim 33, wherein said animation includes random movement of the actual medical instrument and random movement of the actual human organ.

35. A method for teaching a particular skill required for performance of an actual medical procedure to a student. the actual medical procedure being performed with an actual medical instrument on an actual organ with visual feedback. the method comprising the steps of:

(a) providing a simulated instrument for simulating said actual medical instrument;

(b) providing a simulated organ for simulating said actual organ;

(c) abstracting a portion of the visual feedback of the actual medical procedure;

(d) providing said portion of the visual feedback for simulating the visual feedback; and

(e) manipulating said simulated instrument within said simulated organ by the student according to said portion of the visual feedback, such that a motion of said simulated instrument is the skill taught to the student.

36. The method of claim 35, wherein said portion of the visual feedback includes substantially fewer visual details than the visual feedback of the actual medical procedure.

37. The method of claim 36, wherein said simulated organ is a simulation of a gastro-intestinal tract, and said simulated instrument is a simulation of an endoscope.

38. The method of claim 37, wherein said portion of the visual feedback includes only a geometrical shape of an interior of said gastro-intestinal tract.

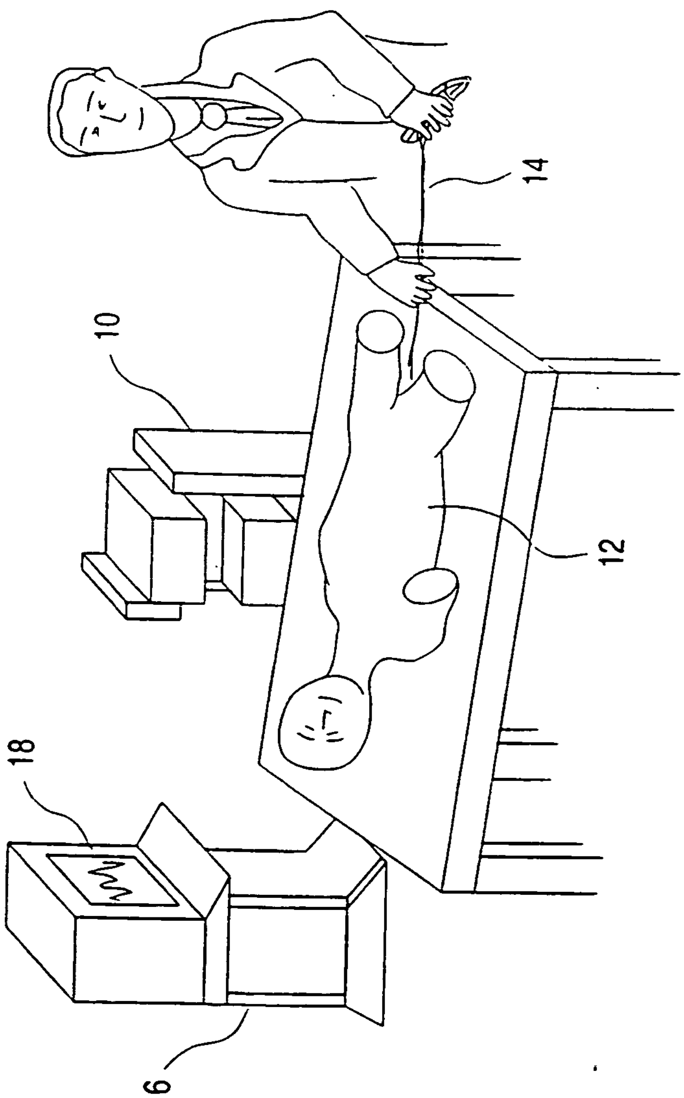


FIGURE 1

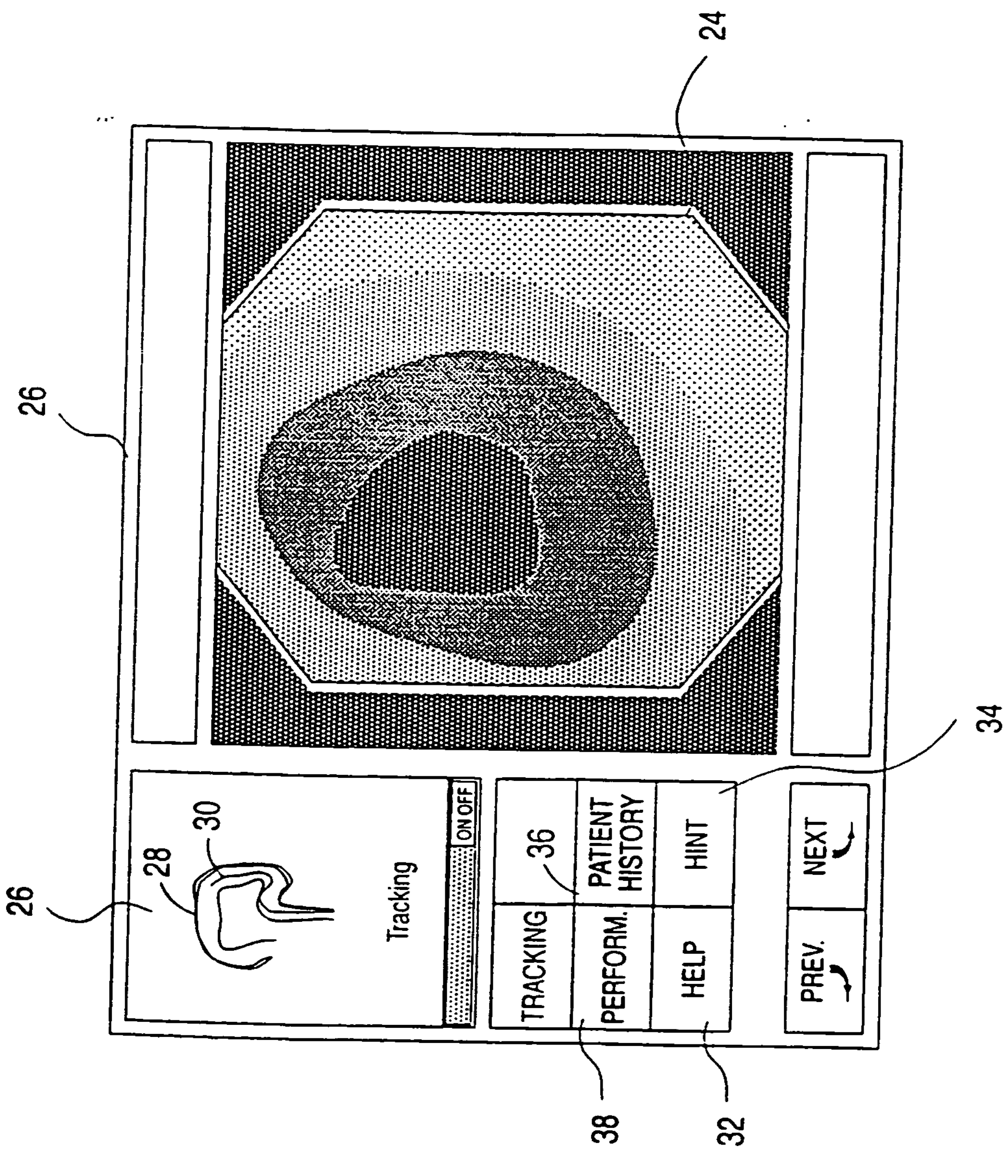

24
26
26
28
30
Tracking
ON OFF
TRACKING
36
PATIENT HISTORY
PERFORM.
HELP
HINT
PREV.
NEXT
34
38
32

FIGURE 2

Figure 3A

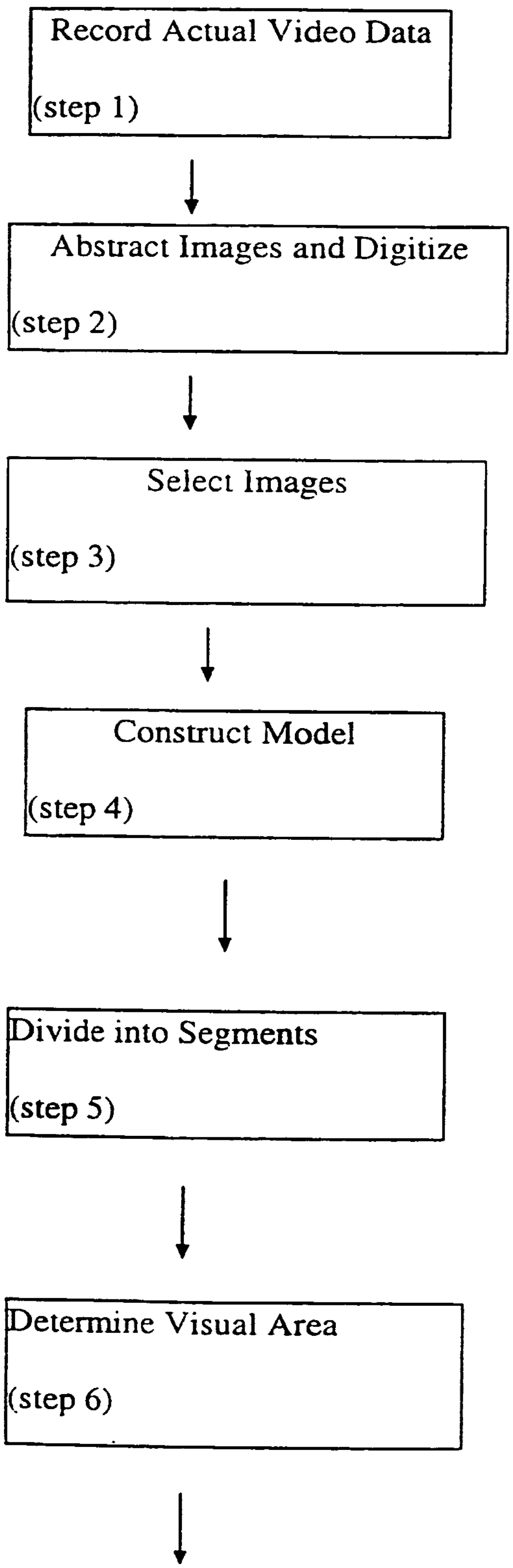
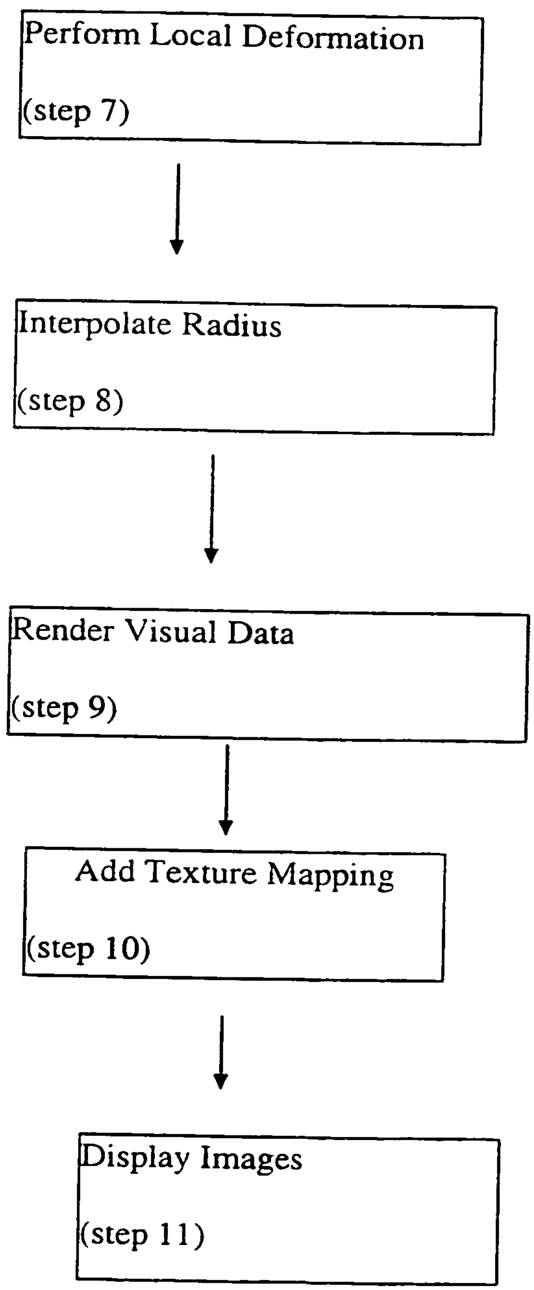

Record Actual Video Data
(step 1)
Abstract Images and Digitize
(step 2)
Select Images
(step 3)
Construct Model
(step 4)
Divide into Segments
(step 5)
Determine Visual Area
(step 6)

Figure 3A (con't)



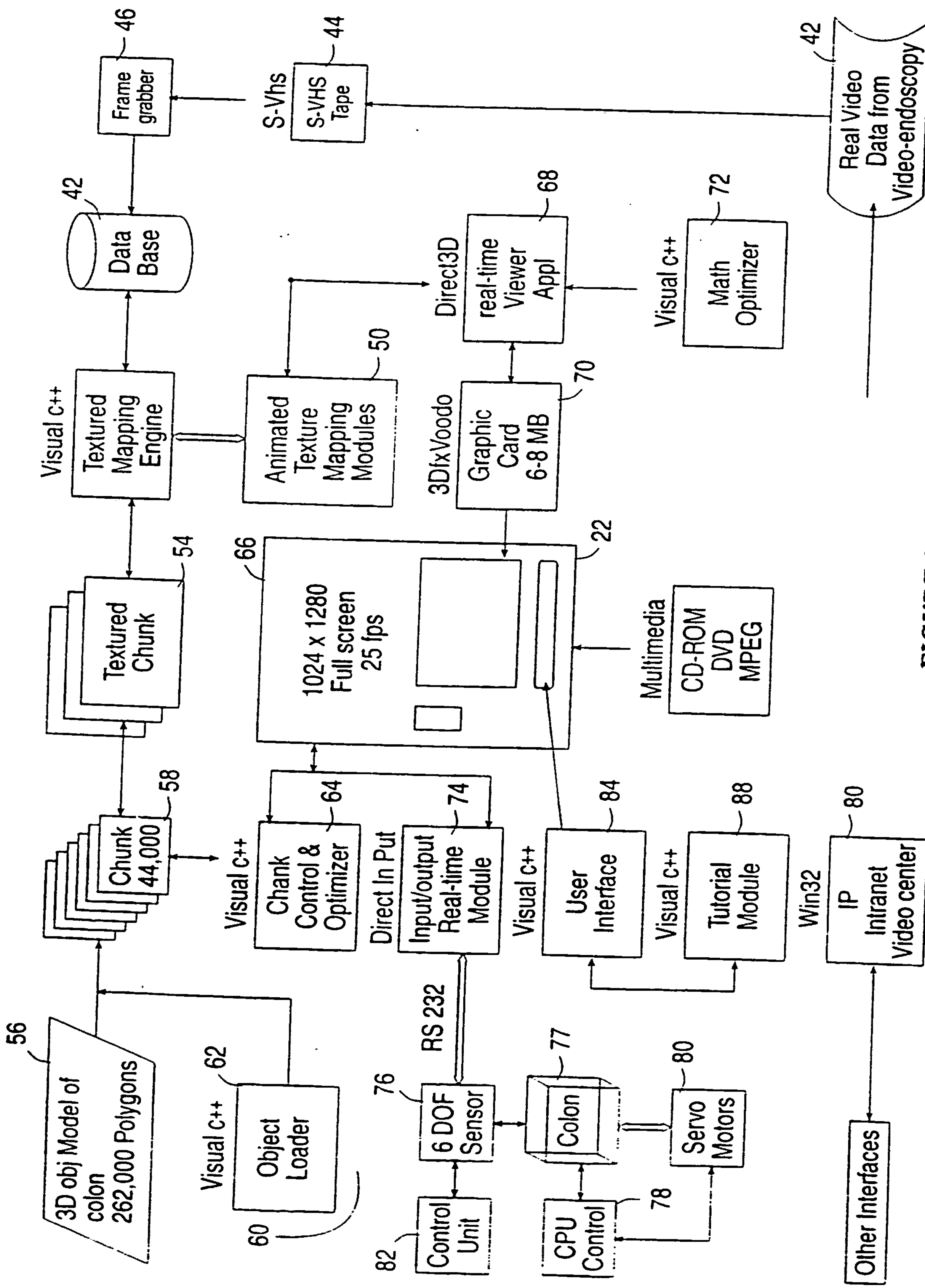

46
Frame grabber
S-Vhs
44
S-VHS Tape
42
Real Video Data from Video-endoscopy
42
Data Base
Visual c++
Textured Mapping Engine
Animated Texture Mapping Modules
50
Direct3D
real-time Viewer Appl
68
Visual c++
Math Optimizer
72
3DfxVoodo
Graphic Card 6-8 MB
70
Textured Chunk
54
66
1024 x 1280 Full screen 25 fps
22
Multimedia
CD-ROM DVD MPEG
Chunk 44,000
58
Visual c++
Chank Control & Optimizer
64
Direct In Put
Input/output Real-time Module
74
Visual c++
User Interface
84
Visual c++
Tutorial Module
88
Win32
IP Intranet Video center
80
56
3D obj Model of colon 262,000 Polygons
Visual c++
Object Loader
62
60
RS 232
76
6 DOF Sensor
77
Colon
80
Servo Motors
82
Control Unit
CPU Control
78
Other Interfaces

FIGURE 3B

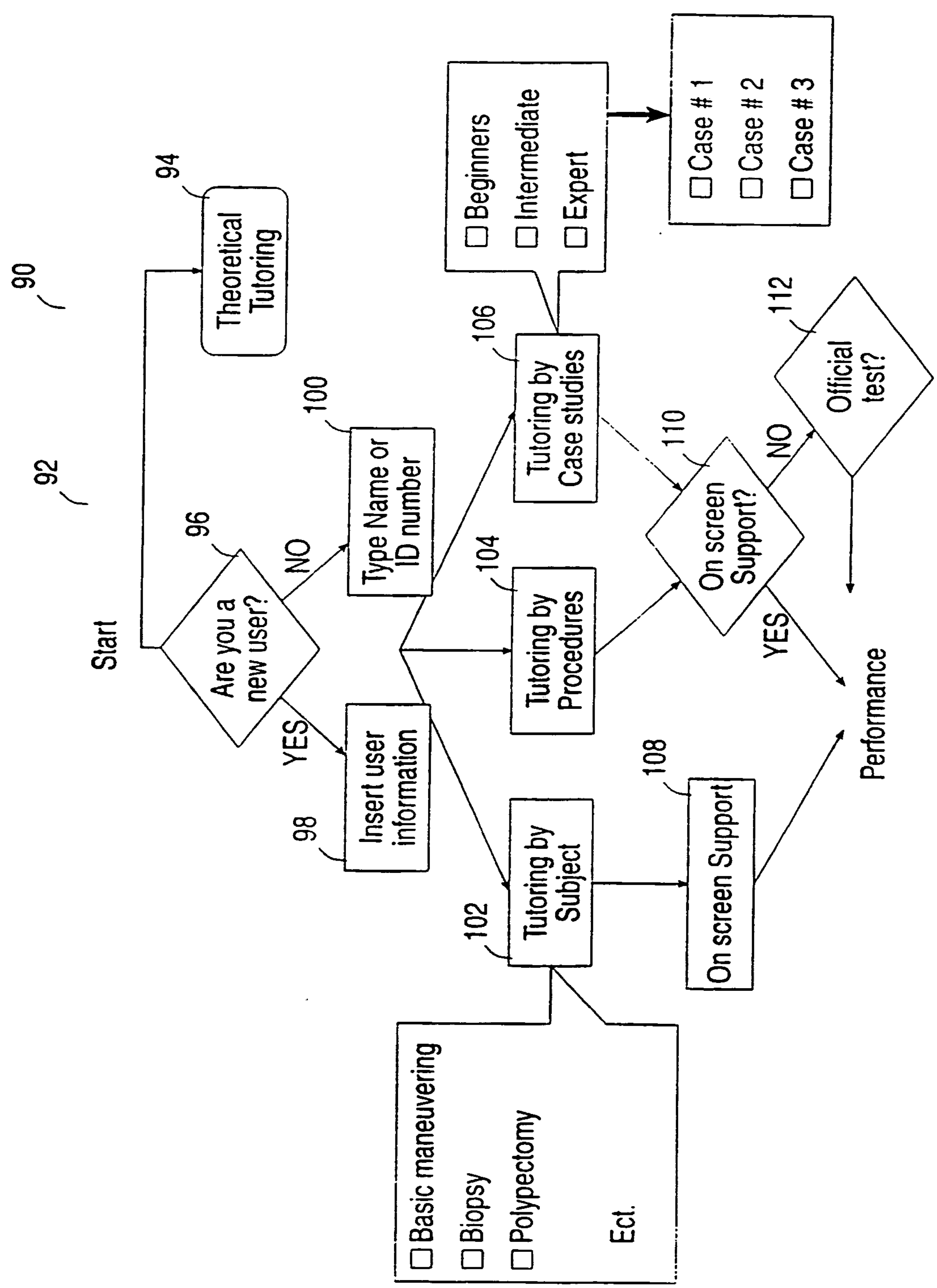

90
92
Start
Are you a new user?
96
NO
YES
Type Name or ID number
100
Insert user information
98
Theoretical Tutoring
94
Tutoring by Case studies
106
Tutoring by Procedures
104
Tutoring by Subject
102
Beginners
Intermediate
Expert
Case # 1
Case # 2
Case # 3
On screen Support?
110
NO
YES
Official test?
112
Performance
On screen Support
108
Basic maneuvering
Biopsy
Polypectomy
Ect.

FIGURE 4

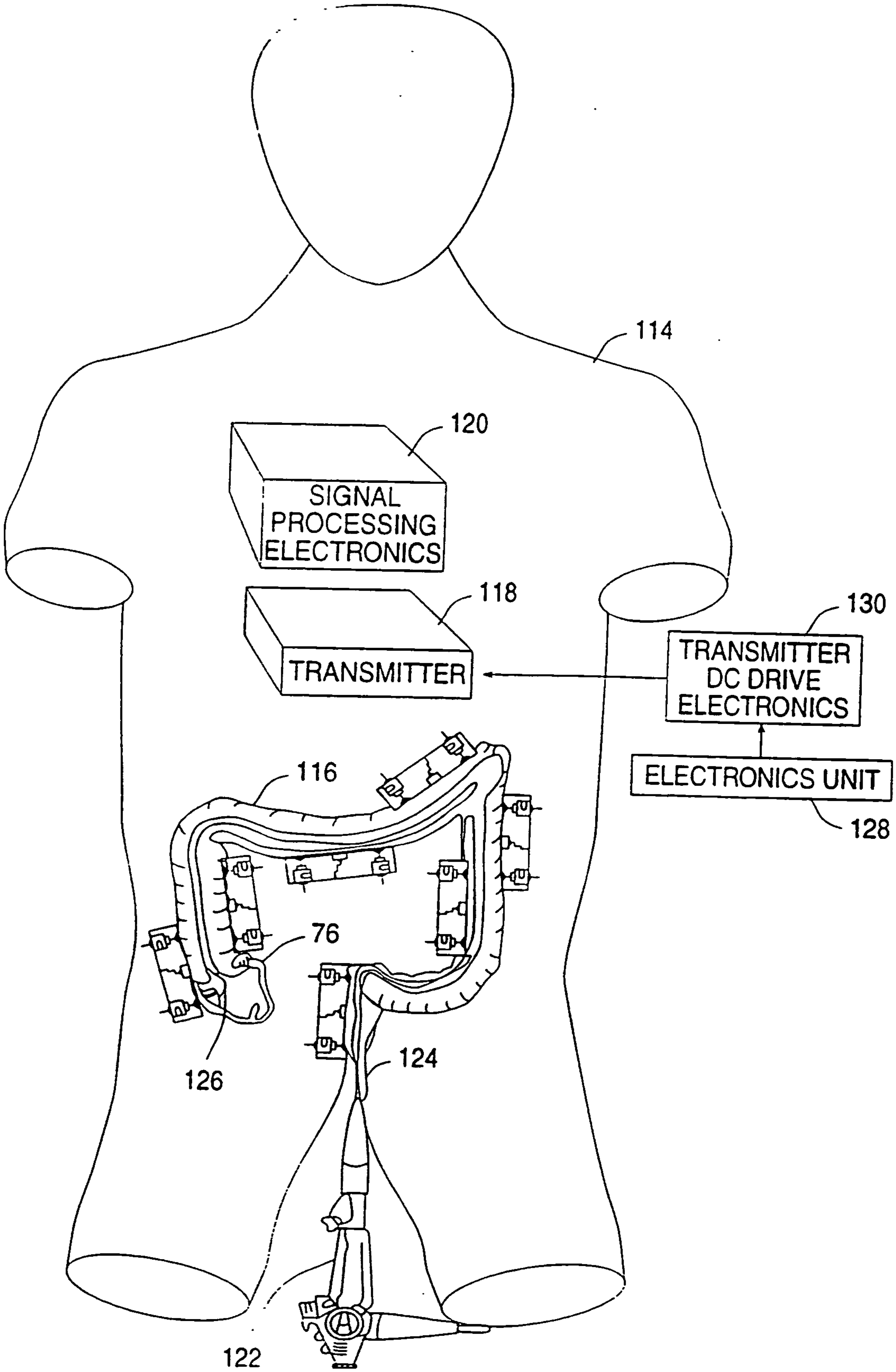

114
120
SIGNAL PROCESSING ELECTRONICS
118
TRANSMITTER
130
TRANSMITTER DC DRIVE ELECTRONICS
ELECTRONICS UNIT
128
116
76
126
124
122

FIGURE 5A

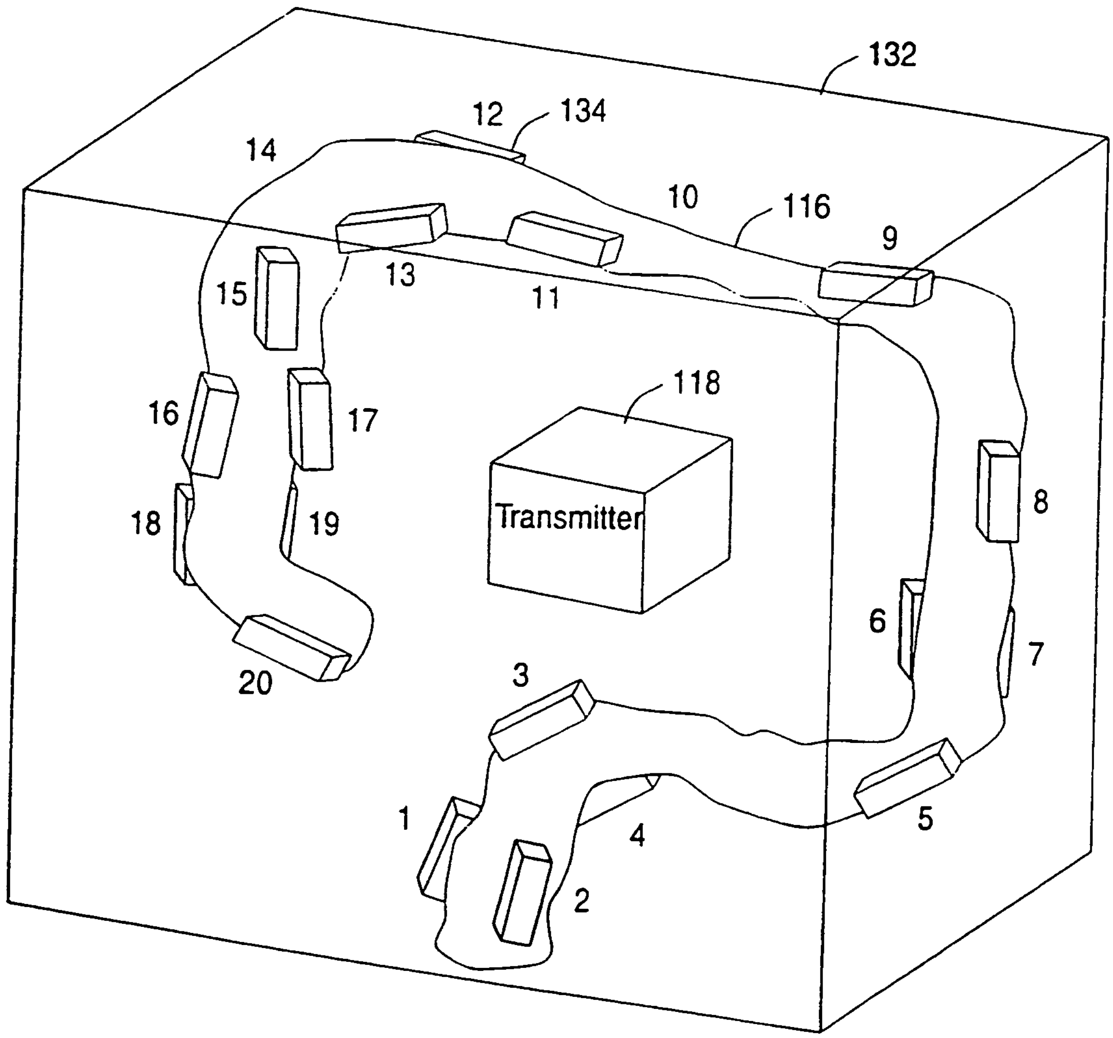

132
12
134
14
10
116
9
13
11
15
118
16
17
8
Transmitter
18
19
6
7
20
3
1
4
5
2

FIGURE 5B

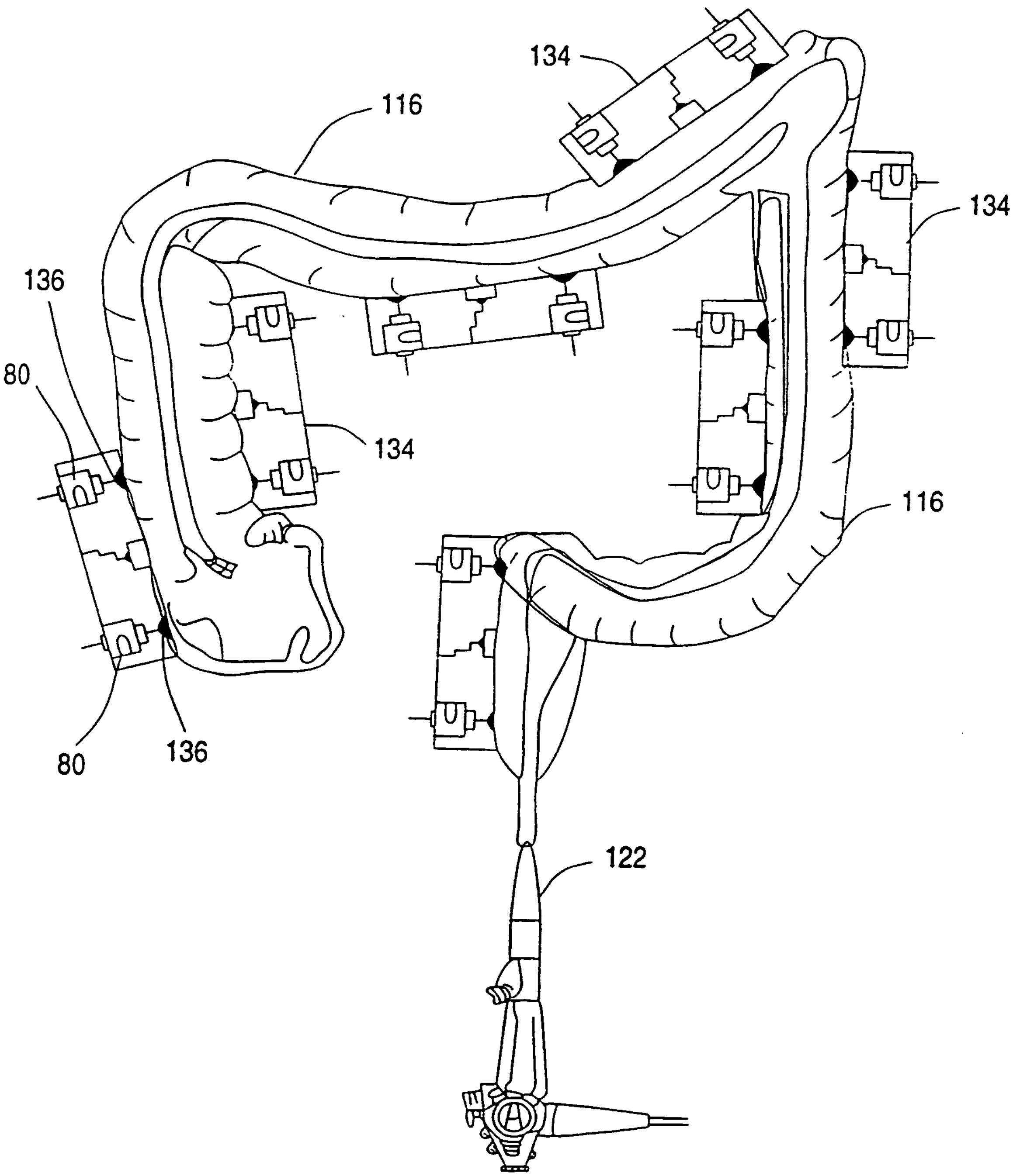


FIGURE 6A

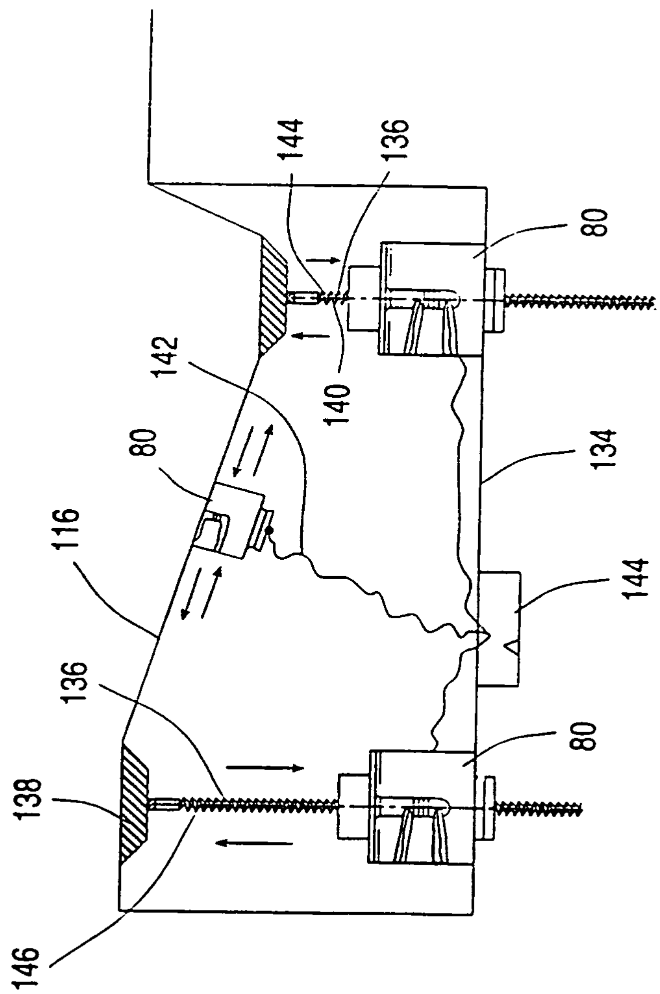


FIGURE 6B

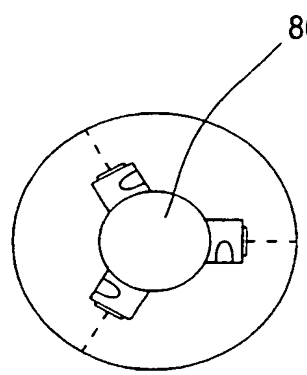


FIGURE 6C

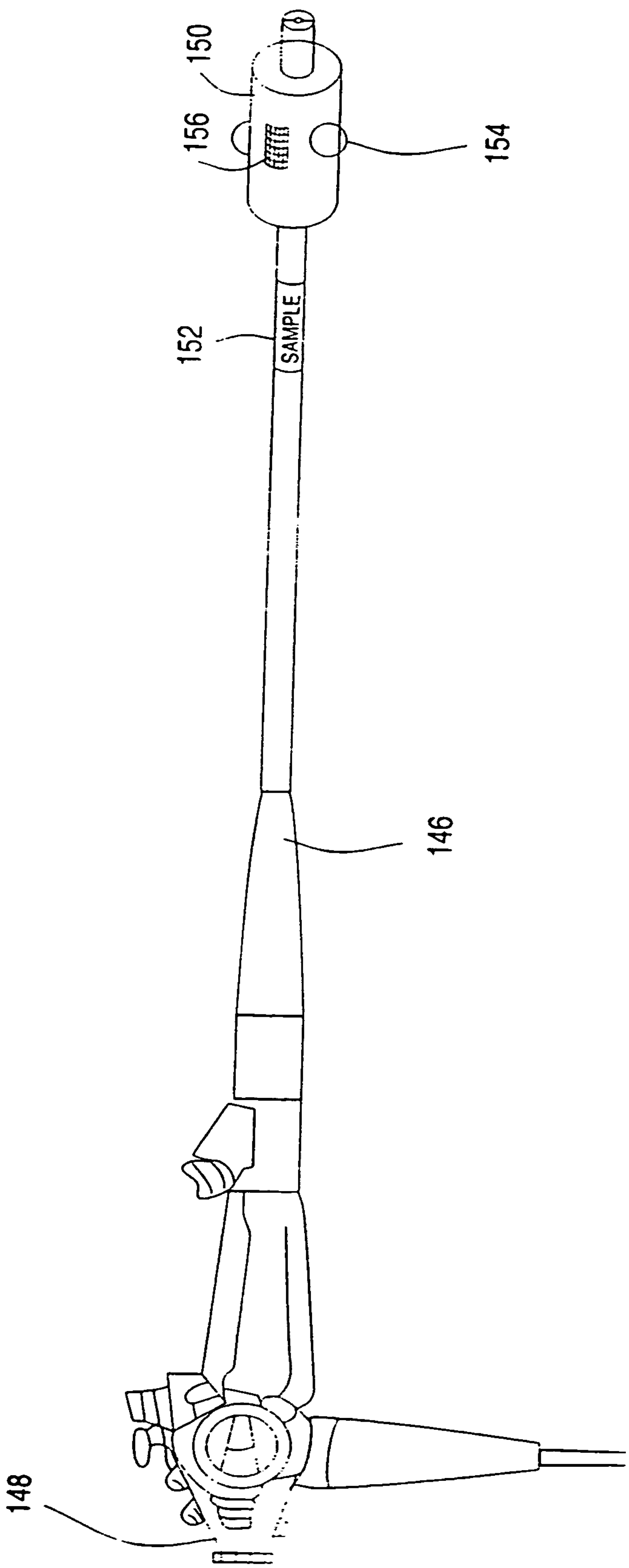


FIGURE 7A

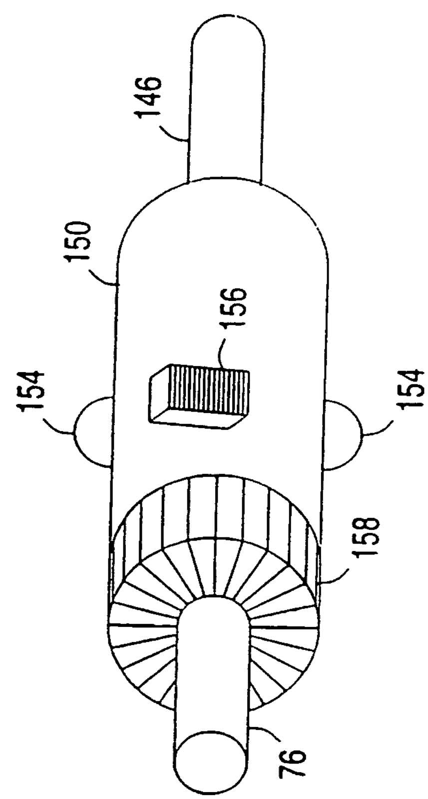


FIGURE 7B

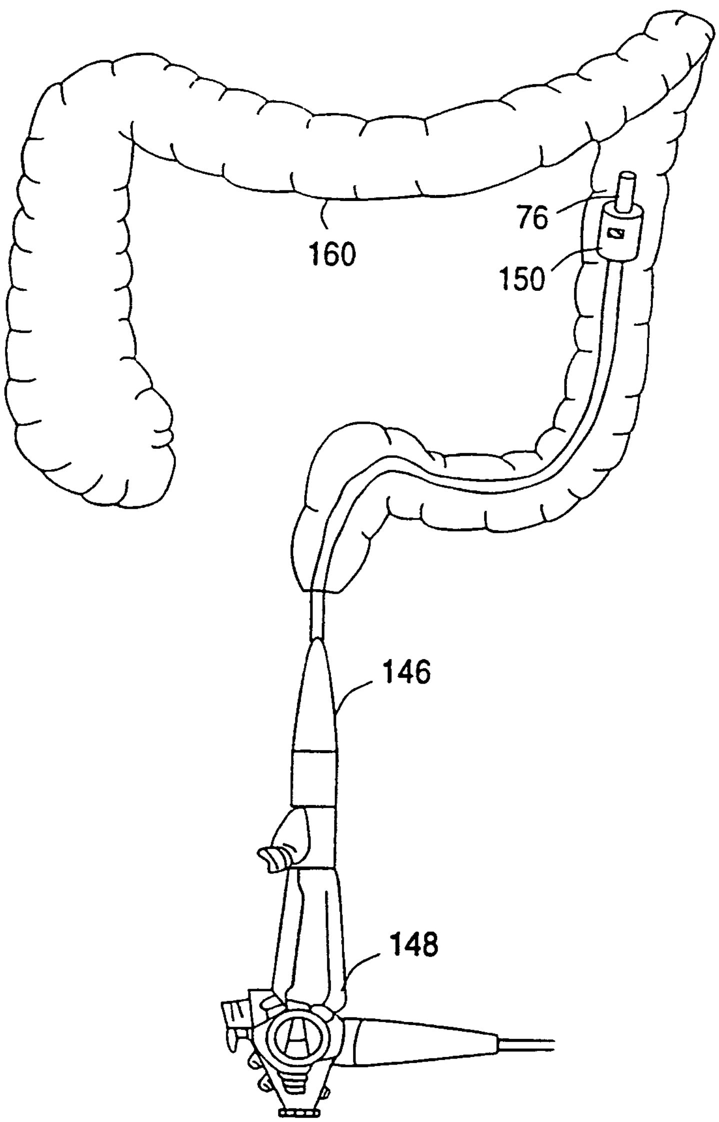


FIGURE 7C

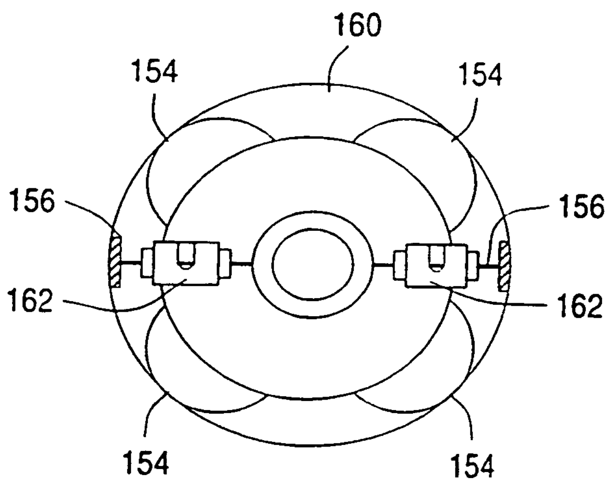


FIGURE 7D

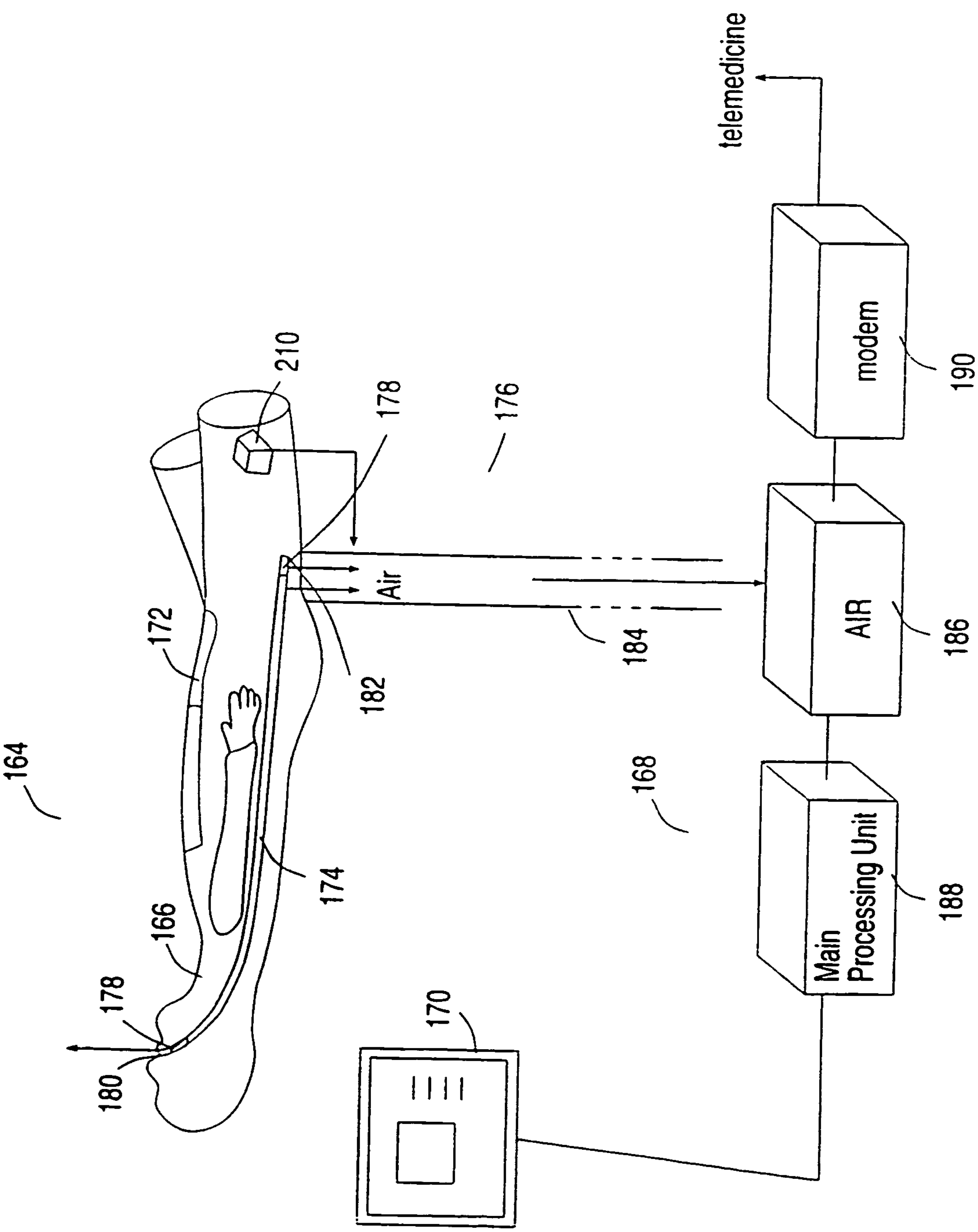

telemedicine
modem
190
AIR
186
Main Processing Unit
188
Air
210
178
176
172
182
184
164
168
174
166
178
180
170

FIGURE 8A

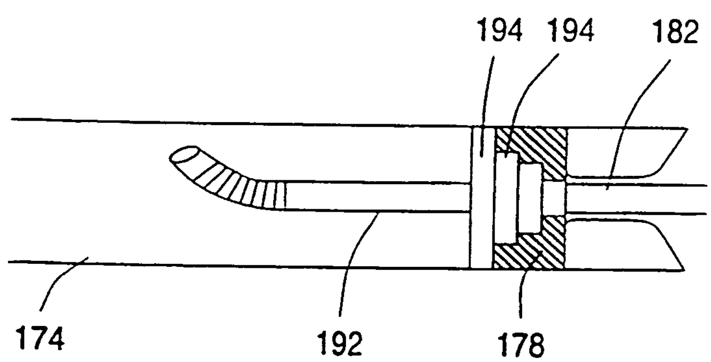


FIGURE 8B

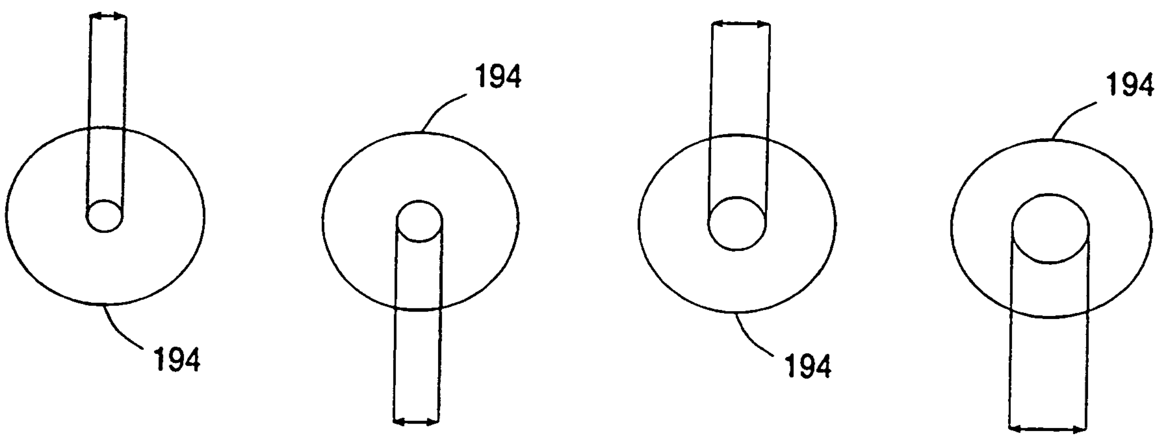


FIGURE 8C

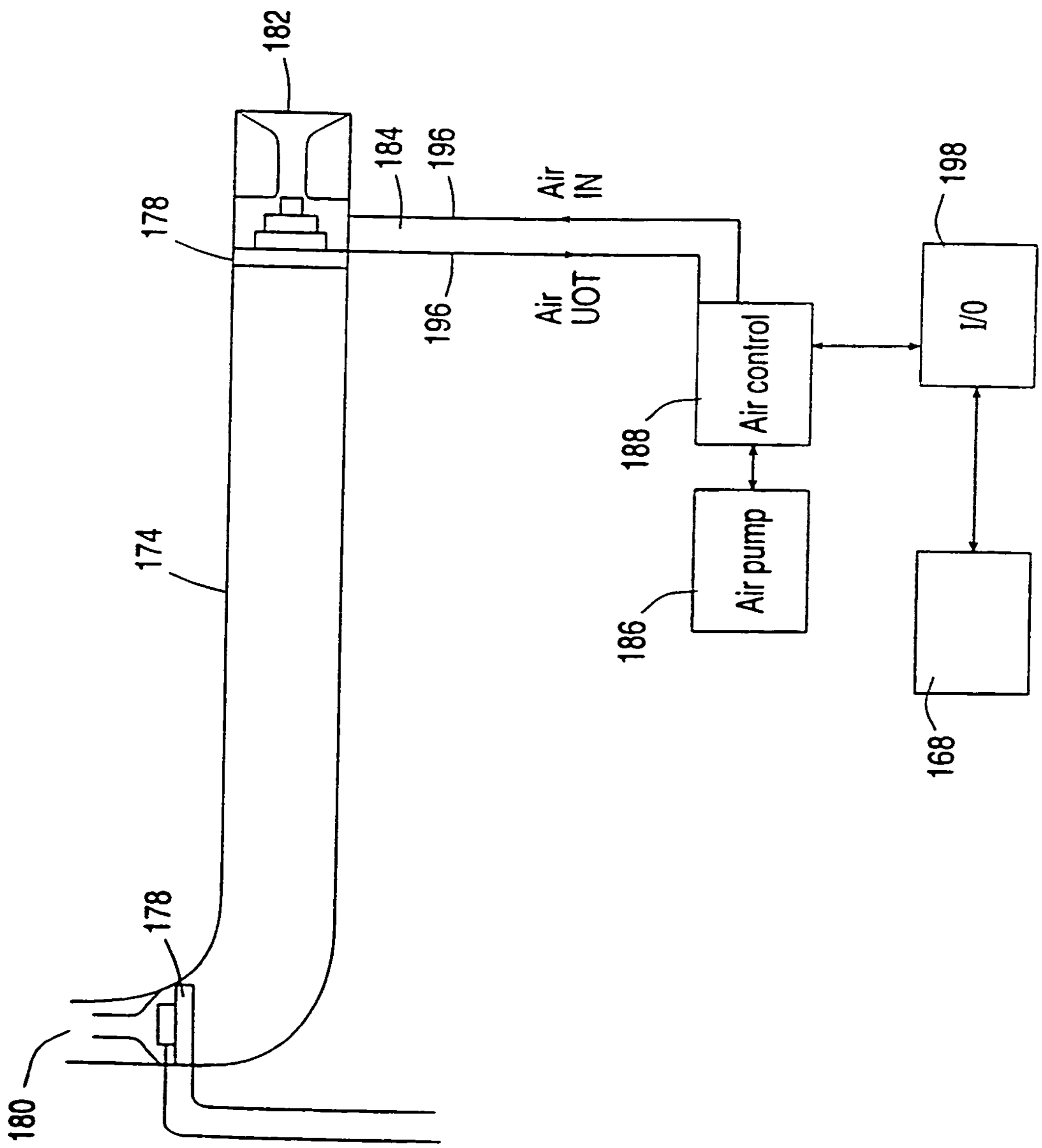

182
178
184
196
Air
IN
Air
UOT
196
198
I/O
Air control
188
Air pump
186
174
168
178
180

FIGURE 8D

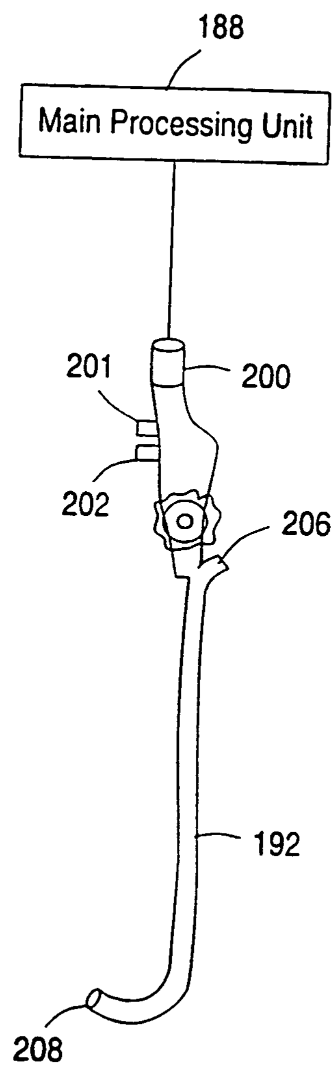


FIGURE 8E

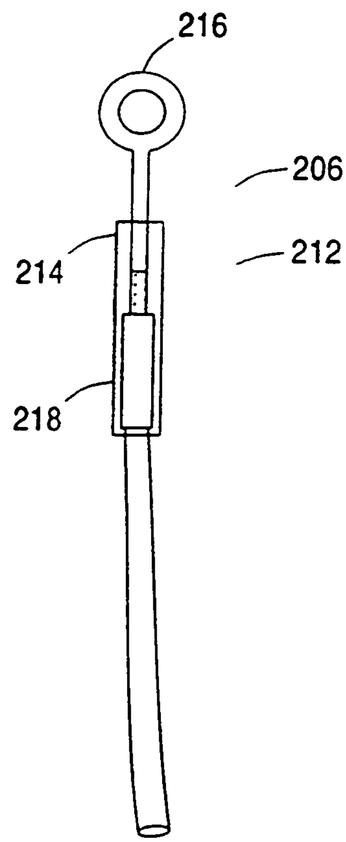


FIGURE 9A

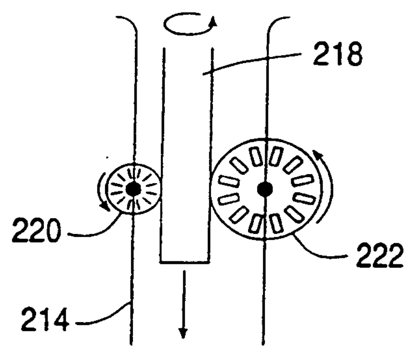


FIGURE 9B

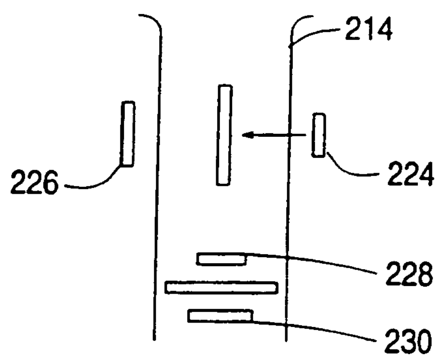


FIGURE 9C

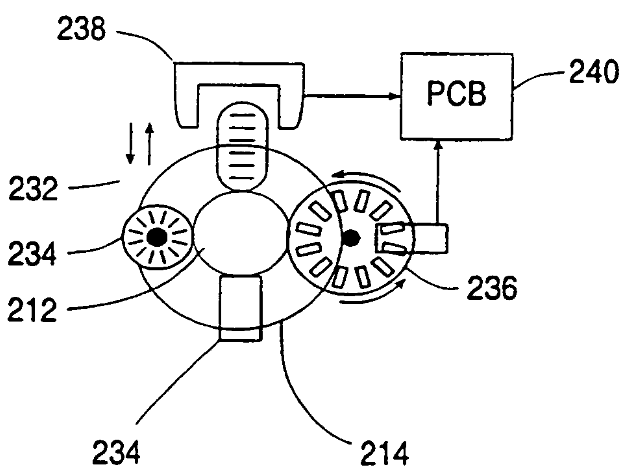


FIGURE 9D

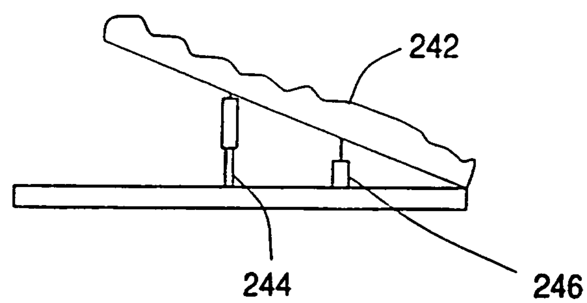


FIGURE 9E

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 99/00028

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G09B23/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G09B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 30885 A (GILLIO ROBERT G) 3 October 1996 see page 11, line 22 - page 14, line 11 see page 18, line 28 - page 27, line 19; claims 1-48 ---	1,2,4,5, 13, 15-18, 22,23, 28-31, 35,37
A	WO 96 28800 A (HIGH TECHSPLANATIONS INC) 19 September 1996 see the whole document --- -/--	1-12,15, 16,18, 25,28, 30-33

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 May 1999	19/05/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Gorun, M

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